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FOREWORD

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INTRODUCTION:

Halofantrine HCl is an antimalarial drug approved by the FDA for the treatment of mild to moderate malaria caused by *Plasmodium falciparum* or *Plasmodium vivax*(1). The present study was designed to investigate the safety, tolerance and pharmacokinetics of halofantrine HCl given in multiple doses in a Phase I study as part of the overall development of halofantrine as a *prophylactic* antimalarial drug.

RATIONALE FOR STUDY:

Mefloquine HCl and doxycycline hyclate are the only Department of Defense (DOD) pharmaceutical preparations currently approved for prophylaxis against chloroquine-resistant *Plasmodium falciparum* (2). Each of these prophylactic agents has its own spectrum of side-effects that may limit its use in individual patients. In addition, changing resistance patterns worldwide necessitates the development of additional chemoprophylactic agents against this potentially deadly disease. Halofantrine may show promise as an alternative prophylactic therapy, however a number of clinical reports have suggested possible cardiotoxicity of halofantrine in the form of electrocardiographic QT prolongation and associated torsade de pointe arrhythmia(3-6). Therefore careful reevaluation of halofantrine safety when it is being considered for use as prophylaxis in healthy people is necessary.

This Phase I safety and tolerance study was designed to evaluate halofantrine given daily at the maximal dose for which absorption is linear and for which there is limited safety data. The period of dosing for this Phase I safety and tolerance study corresponded to the length of time that dosing would be required for a subsequent Phase IIa experimental sporozoite challenge study, dose-optimization study.

STUDY OBJECTIVES:

The prospectively defined objectives of this Phase I study were as follows:

1. To evaluate the safety and tolerance of halofantrine hydrochloride given over time to healthy adults.
2. To characterize the variability of multi-dose halofantrine pharmacokinetics over time in healthy adults.
3. To correlate pharmacodynamics (electrocardiographic QT intervals) with pharmacokinetics (plasma concentrations of halofantrine/desbutylhalofantrine).

STUDY DESIGN:

The study design was a randomized, double-blind, placebo-controlled Phase I safety and tolerance study. Twenty-one healthy volunteers were randomly assigned to receive

halofantrine or placebo. Initially it was planned to study 16 subjects, with 12 subjects to receive active drug (halofantrine) and 4 subjects to receive placebo, however due to subject drop outs prior to study completion, the number to be enrolled was increased to increase the number of subjects who completed the entire study. The blind was maintained with the increase in sample size accomplished by stratified randomization. Subjects were dosed daily for 42 days with 500 mg halofantrine hydrochloride. Subjects were fasted for at least 2 hours prior to and 2 hours following the oral dose. The initial 21 days of drug administration were done with subjects confined as inpatients to the Georgetown University Medical Center Clinical Research Center and during the remaining 21 days of drug administration the subject reported daily to the Clinical Research Center for medical assessment and supervised drug administration. The subjects were then followed periodically for the next 4 1/2 months with medical assessments and pharmacokinetic sampling at the Clinical Research Center.

CONDUCT OF THE STUDY:

The study was conducted at the Georgetown University Clinical Research Center at Georgetown Medical Center, 3800 Reservoir Road NW, Washington, DC. Each subject was an inpatient for 3 weeks during the period between December 21, 1995 and December 27, 1996. The last subject completed the study June 3, 1997. The Principal Investigator was Darrell R. Abernethy, M.D., Ph.D., who is Director of the Georgetown Medical Center Clinical Research Center, Professor of Medicine and Pharmacology, and Director of the Division of Clinical Pharmacology at Georgetown University. Collaborative Investigators included David L. Wesche, M.D., Ph.D. and Brian G. Schuster, M.D., of the Division of Experimental Therapeutics, Walter Reed Army Institute of Research, David Flockhart, M.D., Ph.D., and Jean Barbey, M.D., of the Division of Clinical Pharmacology at Georgetown University Medical Center.

The protocol and informed consent for this study were reviewed and approved by the Georgetown University Institutional Review Board August 1, 1995. Initial recruitment was by word of mouth, however to complete enrollment newspaper advertisement was used. Proposed advertisement for the study was reviewed and approved March 12, 1996. There was also approval of the protocol and informed consent form by the U.S. Army Surgeon General's Human Subjects Research Review Board. Twenty-one healthy male and female subjects were recruited by word of mouth and advertisement in the Washington Post newspaper. All subjects met the protocol inclusion criteria and did not meet the protocol defined exclusion criteria. These were:

Inclusion criteria:

1. Aged 18-45 years inclusive
2. Male or non-pregnant, non-lactating females
3. Weight within 20% of ideal body weight as defined by Metropolitan Life Tables
4. Normal history and physical examination
5. Normal serum chemistries including Mg++

6. Normal CBC
7. Negative HIV screen
8. Negative hepatitis screen
9. Negative serum beta-HCG pregnancy test (females only)
10. Normal electrocardiogram
11. Normal chest X-ray
12. Normal pulmonary function tests with normal DLCO2
13. Negative urine drug screen
14. Normal urinalysis
15. Normal TSH
16. Available for the full duration of the study and willing to comply with study procedures
17. Provision of written informed consent

Exclusion criteria: Any subject with:

1. History of serious medical problems, including any kind of heart disease
2. Allergy to halofantrine or related drugs
3. Taken any medication one week prior to study
4. Donated blood or participated in another investigational drug study within the past 2 months
5. History of alcohol or drug abuse
6. Cigarette smoking or use of any tobacco product
7. Pregnancy, unwillingness to use adequate contraception, or the desire to become pregnant within 6 months of the last dose of study drug
8. Prior upper gastrointestinal surgery
9. HIV positivity or other clinically significant laboratory abnormalities including hyperlipidemia
10. Inability to speak or understand English
11. Unusual dietary habits

Each of the subject volunteers also had a screening physical examination and laboratory study as outlined in the protocol. Any candidate with significant clinical or laboratory abnormality was excluded from participation and referred for appropriate health care follow-up.

Demographics of the 21 subject participants are outlined in Table 1. In summary, they ranged in age for 21-44 years, there were 18 males and 3 females, 8 Caucasian and 13 Black, their weight range was 63-96 kg, and their height range was 62-73 inches.

Subjects were randomized to receive either active or placebo halofantrine in a 4:1 ratio with the randomization blinded and maintained by Dr. Mark Sale, a member of the Division of Clinical Pharmacology at Georgetown Medical Center. The randomization allocation of subject participants is outlined in Table 2. The test material was halofantrine hydrochloride 250 mg tablets. The material was provided by the US Army, however the

original source was noted to be SmithKline Beecham Pharmaceuticals, Welwyn Garden City, Herts, U.K. The tablets were noted to be lot #G1905/V001.

All drug doses were administered in the morning following at least 2 hours fast, with fasting continued for 2 hours following the drug administration. The first 21 daily doses were administered while the subjects were confined the inpatient unit. On day 22 the subjects were discharged from the inpatient unit and they returned daily for their morning observed dose from day 22 to day 41. At that time they were readmitted to the inpatient unit to receive the last dose of halofantrine and have clinical evaluation, safety laboratory determinations, and blood sampling for pharmacokinetic evaluation. On day 43 the subjects were discharged from the inpatient unit to return to the outpatient area on study days 44, 45, 48, 51, 54, 57, 72, and 180.

Subjects 001, 003, 006, 007, 009, 012, 013, 015, 019, 020, and 021 completed the entire 180 days of the study. Subject 017 received only 2 doses of drug, therefore safety information was collected, however this subject was not included as one of the 20 with sufficient data for some evaluation. The other subjects, 002, 004, 005, 008, 010, 011, 014, 016, and 018 completed various proportions of the study before dropping out (Table 3). No subjects were discontinued for adverse events, however 3 adverse events, gastroenteritis (subject 002), skin rash (subject 006), and headaches (subject 011) were noted. The gastroenteritis was associated in time with a food ingestion (about 6 hours later) that seemed the most likely cause, although drug exposure could not be ruled out. The skin rash disappeared while the subject remained on drug and the subject completed the study, therefore it was deemed unlikely to be related to drug exposure. The headaches were temporally related to drug exposure for several days and were deemed to be likely related to drug exposure. An outline of study participation by the subjects is noted in Table 3.

Blood sampling for pharmacokinetic analysis and electrocardiograms for QTc analysis were obtained as follows:

| <u>Day</u> | <u>Time after dose (hr)</u> |
|------------|-----------------------------|
| 1 | predose (1/2 hr) |
| 1 | 0.5 |
| 1 | 1 |
| 1 | 2 |
| 1 | 3 |
| 1 | 4 |
| 1 | 6 |
| 1 | 8 |
| 1 | 10 |
| 1 | 12 |
| 2 | predose |
| 3 | predose |
| 4 | predose |
| 4 | 2 |
| 4 | 4 |
| 4 | 6 |
| 4 | 8 |
| 4 | 12 |
| 5 | predose |
| 6 | predose |
| 7 | predose |
| 7 | 2 |
| 7 | 4 |
| 7 | 6 |
| 7 | 8 |
| 7 | 12 |
| 8 | predose |
| 9 | predose |
| 10 | predose |
| 11 | predose |
| 12 | predose |
| 13 | predose |
| 14 | predose |
| 14 | 2 |
| 14 | 4 |
| 14 | 6 |
| 14 | 8 |
| 14 | 12 |

| <u>Day</u> | <u>Time after dose (hr)</u> |
|------------|-----------------------------|
| 15 | predose |
| 16 | predose |
| 17 | predose |
| 18 | predose |
| 19 | predose |
| 20 | predose |
| 21 | predose |
| 21 | 2 |
| 21 | 4 |
| 21 | 6 |
| 21 | 8 |
| 21 | 12 |
| 25 | predose |
| 29 | predose |
| 32 | predose |
| 36 | predose |
| 39 | predose |
| 42 | predose |
| 42 | 0.5 |
| 42 | 1 |
| 42 | 2 |
| 42 | 3 |
| 42 | 4 |
| 42 | 6 |
| 42 | 8 |
| 42 | 10 |
| 42 | 12 |
| 43 | am |
| 44 | am |
| 45 | am |
| 48 | am |
| 51 | am |
| 54 | am |
| 57 | am |
| 72 | am |
| 180 | am |

Each sampling time point, scheduled and actual, is listed in Table 4. As can be seen, the inpatient samples were obtained within a few minutes of the scheduled time, with outpatient samples for the most part within 1-2 hours of the scheduled time. For pharmacokinetic samples that deviate significantly from the scheduled time, the analysis uses the actual time of collection for purposes of calculation. All blood samples were

centrifuged in a refrigerated centrifuge promptly, the plasma separated, and stored at -70 C until time of shipment. All samples were shipped on dry ice.

Analysis of electrocardiographic data was as follows. All ECGs were 12 lead with a 15 second 3-lead rhythm strip (I, aVF, V2). The chart speed for recording the 12 lead ECG was 25 mm/sec, the speed for the rhythm strip was 50 mm/sec. Two copies of each ECG were recorded, one for the chart and one for interpretation. For each ECG the RR interval and QT interval were measured for the first 3 consecutive normal and technically acceptable complexes and the results were averaged. If the RR interval was greater than 500 msec, QTc was calculated according to the Bazett formula(7). If the RR interval was less than 500 msec, the Fridericia correction was used(8). QT interval measurement was based on a modification of the method of Lepschkin et al(9). The ECG tracings were placed on a digitizing pad and a cross-hair type pointing device was used to mark the beginning and the end of each interval. The data were transmitted to and stored on computer. The QT duration was measured on the rhythm strips from three leads simultaneously with use of the earliest beginning of the QRS complex to the end of the longest T wave in any of the three simultaneous leads. The end of each T wave was determined by drawing a tangent to the steepest portion of the downsloping T wave. The point at which this tangent intersected with the isoelectric line was used to designate the end of the T wave.

In addition to the above mentioned procedures, questioning regarding adverse reactions and subjective symptomatology, vital sign determinations and determination of laboratory safety parameters were performed as outlined in the study protocol. Deviations have been noted in the specific case report forms. These data are recorded for each subject in the subject's case report form. Copies of case report forms have been appropriately completed for each subject and have been periodically reviewed by the USAMMDA monitor. These forms are on file and available at the Georgetown University Clinical Research Center.

Periodically, according to the protocol-defined procedure, plasma samples were shipped on dry ice to Dr. Emil Lin at the Drug Studies Unit, School of Pharmacy, University of California at San Francisco. Quality control and reporting of plasma concentration data was monitored separately from clinical site monitoring.

RESULTS:

The study findings will be separated into 5 sections as follows: (1) Clinical Adverse Experiences, (2) Laboratory Safety Parameters, (3) Pharmacokinetic Results, (4) Pharmacodynamic [Electrocardiographic] Results, and (5) Pharmacokinetic / Pharmacodynamic Concentration Effect Relationships.

1. Clinical Adverse Experiences. Subject 002 (21 year old Black male) experienced stomach cramping, diarrhea, and fever for 4 days starting day 31 of the study. This began a few hours after ingestion of some possibly contaminated food. The subject stated he had

eaten salmon with a friend and the friend had become ill with similar symptoms. Evaluation on day 32 revealed mild abdominal tenderness and no other significant findings. At that time CBC showed 8000 WBC, Hb 14.2 and Hct 42.3. Symptoms subsided spontaneously on day 35. This subject was receiving halofantrine. He discontinued study on day 36 for personal reasons. Subject 006 (26 year old White male) developed a localized skin rash on day 11. Local care was administered and by day 15, while the subject remained on study the rash resolved. This subject was receiving placebo. Subject 011 (43 year old Black Hispanic female) complained of a throbbing headache on day 7. This was considerably relieved by a 650 mg dose of acetaminophen. The headache recurred on days 10, 12, 19, 21, and 22. Physical examination was unrevealing at the various evaluations during this series of headaches. This subject was receiving halofantrine. The subject did not subsequently complain of headache. Based on the history and examination, I deemed the subject 002 and subject 006 events to be unlikely to be related to halofantrine, and the subject 011 event to be probably related to halofantrine.

2. Laboratory Safety Parameters. Screening laboratory parameters for inclusion into the study are shown in Table 5 and include Drug Screen, Chest X-ray, Pulmonary function tests (screen and day 42), TSH, HIV, Hepatitis Surface Antigen (HBsAg), Hepatitis C (HbC), and Hepatitis C antibody (HbC antibody).

Vital signs during the course of the study are shown in Table 6(a-e) and include systolic blood pressure, diastolic blood pressure, heart rate, temperature, and weight. Each of these parameters is followed by 2 figures that plot the values and variance. This first figure shows the data in a linear array and includes maximum and minimum values, while the second figure shows the data with standard deviation plotted on a true time scale (Figures 1-10). Of interest, systolic and diastolic blood pressure and heart rate tended to be less during the inpatient part of the protocol (days 1-22). Early in the study weight was not measured daily, therefore missing data appear as empty cells in this table.

Beta HCG for female subjects (003, 010, 011) is shown in Table 7 and data are included for the duration of their participation (only 003 completed the study).

Hematological profile during the course of the study is shown in Table 8(a-l) and includes WBC, hemoglobin, hematocrit, RBC, red cell indices (MCV, MCHC, MCH), reticulocyte count, and white cell differential (eosinophils, segmented neutrophils, monocytes, lymphocytes). Values outside of the laboratory normal range are bolded. Each table is followed by a figure which plots the mean, standard deviation, and extreme values for the respective parameter (Figures 11-22). No trend for change in hematological parameters could be discerned during and following drug exposure. Missing data and data not obtained due to subject dropout are shown as empty cells.

Electrolytes during the course of the study are shown in Table 9(a-e) and include sodium, chloride, potassium, carbon dioxide, and glucose. Values outside of the laboratory normal range are bolded. Each table is followed by a figure which plots the mean, standard

deviation, and extreme values for the respective parameter (Figures 23-27). No trend for change in electrolytes, CO₂, or glucose could be discerned during the course of the study. Missing data and data not obtained due to subject dropout are shown as empty cells.

Other chemistries during the course of the study are shown in Table 10(a-s) and include alkaline phosphatase, albumin, total bilirubin, blood urea nitrogen, calcium, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, creatinine, gGT, LDH, magnesium, phosphate, total protein, AST, ALT, and uric acid. Each table is followed by a figure which plots the mean, standard deviation, and extreme values for the respective parameter (Figures 28-45). No trend for change in other chemistries could be discerned during the course of the study. Missing data and data not obtained due to subject dropout are shown as empty cells.

Urinalysis with microscopic examination is shown in Table 11(a-e) and includes casts, occult blood, RBC, WBC, and specific gravity. Each table is followed by a figure which plots the mean, standard deviation, and extreme values for the respective parameter (Figures 46-48). Occult blood noted for subjects 003 and 010 was observed during menses for these female subjects. No trend for change in urinalysis parameters was noted throughout the course of the study.

3. Pharmacokinetics: The pharmacokinetic parameters which could be evaluated with a degree of reliability were accumulation rate constant and accumulation half-life for each of the halofantrine stereoisomers (+Halofantrine and -Halofantrine) and steady state oral clearance for each of the isomers. Accumulation rate constants were determined from all trough (prior to the next dose) concentrations for days 1-45, the time of daily oral dosing of 500 mg/day racemic Halofantrine hydrochloride. Steady state oral clearance was determined from the mean of the measured trough concentrations from dosing days 23-45, which on visual inspection provided a reasonable description of steady state. Fitted functions for each subject, calculated accumulation rate constants and half lives are shown on Figure 49 (a-p). Calculated values were: +Halofantrine; 0.161 ± 0.120 days⁻¹ and 7.01 ± 4.80 days respectively and -Halofantrine; 0.184 ± 0.191 days⁻¹ and 7.25 ± 4.82 days respectively. Similarly steady state concentrations and oral clearance are shown on Figure 50. Observed and calculated values were: +Halofantrine; 88.8 ± 46.2 ng/ml and 139 ± 73.0 L/hr respectively and -Halofantrine; 43.7 ± 17.3 ng/ml and 265.2 ± 135.4 L/hr respectively. It is worth noting that +Halofantrine has markedly higher steady state concentrations across the group and this is reflected in the oral clearance calculation, which is about 1/2 that seen for -Halofantrine.

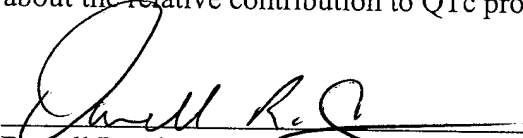
4. Pharmacodynamics (Electrocardiographic Effects): Electrocardiographic parameters during the course of the study are shown in Table 12 (a-d) including heart rate, PR interval, QRS duration, and QTc calculated as described above. Following each table is a plot of mean, standard deviation, and extreme values for each ECG (Figures 51-54). No trend for change in heart rate, PR interval, or QRS duration could be discerned. In contrast, QTc interval tended to be prolonged from baseline in subjects 002, 007, 009,

010, 011, 014, 016, 018, and 021. These subjects were all receiving halofantrine, and none of the subjects receiving placebo had an appreciable change in QTc.

5. Concentration Effect (Pharmacokinetic/Pharmacodynamic) Relationships: Raw data depicting measured ECG QTc and concentrations of the stereoisomers of halofantrine and its major metabolite, desbutylhalofantrine are shown in Table 13 (a-o). Subjects who received placebo of course are not represented as they have no halofantrine concentration determinations. Concentration time plots for isomers of halofantrine and desbutylhalofantrine are shown in Figure 55 (a-o). Linear regressions of +halofantrine and ECG QTc and -halofantrine and ECG QTc are depicted in figures 56-70. It is clear that in most subjects a strong relationship between halofantrine concentration and lengthening QTc exists (Subjects 1,2,4,8,9,10,11,14,15,16,18, and 20) and that there is little relationship for others (Subjects 5,7,19).

CONCLUSIONS:

This halofantrine regimen of 500 mg per os once daily administered in the fasting state for a period of 6 weeks was well tolerated by the subject participants. Clinical adverse effects were few and minor. Laboratory safety profiles showed no evidence of abnormality associated with drug exposure. Electrocardiographic QTc prolongation in the range of 5-15% occurred in most subjects who received halofantrine, and did not occur in subjects who received placebo. In most instances a linear relationship between increasing concentrations of each of the halofantrine stereoisomers and lengthening of the ECG QTc could be demonstrated. Since racemic halofantrine was administered concentrations of each of the isomers covaried, therefore no conclusion can be reached from this study about the relative contribution to QTc prolongation from the respective isomers.


Darrell R. Abernethy, M.D., Ph.D.
Principal Investigator

17 December, 1998
Date

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Table 1

| HALOFANTRINE SUBJECT DEMOGRAPHICS | | | | | | | | | |
|-----------------------------------|----------|--------------|--------|-----|-------------|-------------|------------|--------------|-----------------|
| Subject Number | Initials | Race | Gender | Age | Weight (kg) | Height (in) | Hosp Day 0 | Date Dropped | Study Completed |
| 1 | JKS | W | M | 23 | 64 | 67 | 12/21/95 | | 06/18/96 |
| 2 | BSH | B | M | 21 | 96 | 68 | 12/21/95 | 01/25/96 | |
| 3 * | EJW | W | F | 23 | 68 | 70 | 12/21/95 | | 06/18/96 |
| 4 | WPS | B | M | 27 | 68 | 71 | 01/10/96 | 02/16/96 | |
| 5 | SGA | B | M | 35 | 68 | 70 | 01/10/96 | 02/07/96 | |
| 6 * | JBC | W | M | 26 | 77 | | 01/25/96 | | 07/23/96 |
| 7 | DAN | W | M | 33 | 73 | 68 | 02/15/96 | | 08/13/96 |
| 8 | AYB | B | M | 28 | 64 | 67 | 02/15/96 | 02/25/96 | |
| 9 | GRL | W | M | 38 | 75 | 71 | 02/15/96 | | 08/13/96 |
| 10 | EYJ | B | F | 39 | 75 | 65 | 02/15/96 | 04/09/96 | |
| 11 | C-E | B (Hispanic) | F | 43 | 66 | 52 | 02/23/96 | 04/08/96 | |
| 12 * | HLL | B | M | 37 | 82 | 71 | 03/14/96 | | 09/10/96 |
| 13 * | GLG | W | M | 35 | 63 | 67 | 03/28/96 | | 10/08/96 |
| 14 | DLS | B | M | 43 | 75 | 68 | 03/28/96 | 05/07/96 | |
| 15 | DMK | B | M | 28 | 71 | 63 | 03/28/96 | | 09/24/96 |
| 16 | L-W | B | M | 44 | 77 | 73 | 03/28/96 | 05/11/96 | |
| 17 | LDG | B | M | 21 | 68 | 70 | 08/01/96 | 08/02/96 | |
| 18 | KLS | B | M | 36 | 68 | 69 | 08/01/96 | 10/02/96 | |
| 19 | WSB | W | M | 43 | 82 | 71 | 08/22/96 | | 02/18/97 |
| 20 | K-P | B | M | 22 | 75 | 70 | 10/31/96 | | 04/28/97 |
| 21 * | CAE | W | M | 38 | 92 | 69 | 12/05/96 | | 06/03/97 |
| * denotes Placebo | | | | | | | | | |

Table 2

| RANDOMIZATION CODE | |
|--------------------|--------------|
| Subject No. | Assignment |
| 1 | Halofantrine |
| 2 | Halofantrine |
| 3 | Placebo |
| 4 | Halofantrine |
| 5 | Halofantrine |
| 6 | Placebo |
| 7 | Halofantrine |
| 8 | Halofantrine |
| 9 | Halofantrine |
| 10 | Halofantrine |
| 11 | Halofantrine |
| 12 | Placebo |
| 13 | Placebo |
| 14 | Halofantrine |
| 15 | Halofantrine |
| 16 | Halofantrine |
| 17 | Halofantrine |
| 18 | Halofantrine |
| 19 | Halofantrine |
| 20 | Halofantrine |
| 21 | Placebo |

Table 3

| HALOFANTRINE STUDY PARTICIPATION DATES | | | | |
|--|----------|----------------|--------------|-----------------|
| Subject Number | Initials | Hospital Day 0 | Date Dropped | Study Completed |
| 1 | JKS | 12/21/95 | | 06/18/96 |
| 2 | BSH | 12/21/95 | 01/25/96 | |
| 3 | EJW | 12/21/95 | | 06/18/96 |
| 4 | WPS | 01/10/96 | 02/16/96 | |
| 5 | SGA | 01/10/96 | 02/07/96 | |
| 6 | JBC | 01/25/96 | | 07/23/96 |
| 7 | DAN | 02/15/96 | | 08/13/96 |
| 8 | AYB | 02/15/96 | 02/25/96 | |
| 9 | GRL | 02/15/96 | | 08/13/96 |
| 10 | EYJ | 02/15/96 | 04/09/96 | |
| 11 | C-E | 02/23/96 | 04/08/96 | |
| 12 | HLL | 03/14/96 | | 09/10/96 |
| 13 | GLG | 03/28/96 | | 10/08/96 |
| 14 | DLS | 03/28/96 | 05/07/96 | |
| 15 | DMK | 03/28/96 | | 09/24/96 |
| 16 | L-W | 03/28/96 | 05/11/96 | |
| 17 | LDG | 08/01/96 | 08/02/96 | |
| 18 | KLS | 08/01/96 | 10/02/96 | |
| 19 | WSB | 08/22/96 | | 02/18/97 |
| 20 | K-P | 10/31/96 | | 04/28/97 |
| 21 | CAE | 12/05/96 | | 06/03/97 |

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| Subj | Date Time | Day 1 | Day 1 | Day 1 | Day 1 | Day 1 | Day 1 | Day 1 | Day 1 | Day 1 | Day 1 | Day 2 | Day 3 | Day 4 | Day 4 | Day 4 | Day 4 | Day 4 | |
|------|--------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | | Pre | .5hr | 1hr | 2hr | 3hr | 4hr | 6hr | 8hr | 10hr | 12hr | Pre | Pre | Pre | 2hr | 4hr | 6hr | 8hr | 12hr |
| 12 | Act: | 8:18 | 9:55 | 9:30 | 10:30 | 11:25 | 12:35 | 14:30 | 16:30 | 18:35 | 20:10 | 08:12 | 08:40 | 07:50 | 10:00 | 12:21 | 14:20 | 16:24 | 20:25 |
| 12 | Schd: | 7:45 | 8:45 | 9:15 | 10:15 | 11:15 | 12:15 | 14:15 | 16:15 | 18:15 | 20:15 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 |
| 12 | Diff: | 33 | 70 | 15 | 15 | 10 | 20 | 15 | 15 | 20 | -5 | 27 | 55 | 5 | -15 | 6 | 5 | 9 | 10 |
| 13 | Act: | 8:55 | 9:30 | 10:00 | 11:00 | 12:00 | 13:00 | 15:04 | 17:02 | 19:03 | 21:00 | 08:55 | 09:20 | 08:55 | 11:05 | 13:05 | 14:55 | 16:55 | 21:05 |
| 13 | Schd: | 8:30 | 9:30 | 10:00 | 11:00 | 12:00 | 13:00 | 15:00 | 17:00 | 19:00 | 21:00 | 8:30 | 8:30 | 8:30 | 11:00 | 13:00 | 15:00 | 17:00 | 21:00 |
| 13 | Diff: | 25 | 0 | 0 | 0 | 0 | 0 | 4 | 2 | 3 | 0 | 25 | 50 | 25 | 5 | 5 | -5 | -5 | 5 |
| 14 | Act: | 8:00 | 8:50 | 9:20 | 10:20 | 11:20 | 12:20 | 14:20 | 16:20 | 18:20 | 20:20 | 08:25 | 09:00 | 08:10 | 10:28 | 12:21 | 14:04 | 16:09 | 20:29 |
| 14 | Schd: | 8:00 | 9:00 | 9:30 | 11:30 | 12:30 | 13:30 | 15:30 | 17:30 | 19:30 | 21:30 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 |
| 14 | Diff: | 0 | -10 | -10 | -70 | -70 | -70 | -70 | -70 | -70 | -70 | 25 | 60 | 10 | -2 | -9 | -26 | -21 | -1 |
| 15 | Act: | 8:30 | 9:14 | 9:50 | 10:45 | 11:48 | 12:50 | 14:44 | 16:45 | 18:35 | 20:36 | 08:40 | 08:41 | 08:50 | 10:55 | 12:55 | 14:55 | 16:55 | 20:45 |
| 15 | Schd: | 8:10 | 9:10 | 9:40 | 10:40 | 11:40 | 12:40 | 14:40 | 16:40 | 18:40 | 20:40 | 8:10 | 8:10 | 8:10 | 10:55 | 12:55 | 14:55 | 16:55 | 20:55 |
| 15 | Diff: | 20 | 4 | 10 | 5 | 8 | 10 | 4 | 5 | -5 | -4 | 30 | 31 | 40 | 0 | 0 | 0 | 0 | -10 |
| 16 | Act: | 7:58 | 8:40 | 9:07 | 10:05 | 11:05 | 12:05 | 14:05 | 16:10 | 18:05 | 20:00 | 07:55 | 08:00 | 08:04 | 10:04 | 12:04 | 14:30 | 16:30 | 20:12 |
| 16 | Schd: | 7:30 | 8:30 | 9:00 | 10:00 | 11:00 | 12:00 | 14:00 | 16:00 | 18:00 | 20:00 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 |
| 16 | Diff: | 28 | 10 | 7 | 5 | 5 | 5 | 5 | 10 | 5 | 0 | 25 | 30 | 34 | 4 | 4 | 30 | 30 | 12 |
| 17 | Act: | 8:29 | 9:15 | 9:31 | 10:31 | 11:30 | 12:32 | 14:30 | | | | | | | | | | | |
| 17 | Schd: | 8:00 | 9:00 | 9:30 | 11:30 | 12:30 | 13:30 | 15:30 | 17:30 | 19:30 | 21:30 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 |
| 17 | Diff: | 29 | 15 | 1 | -59 | -60 | -58 | -60 | | | | | | | | | | | |
| 18 | Act: | 8:05 | 9:05 | 9:37 | 10:35 | 11:32 | 12:34 | 14:33 | 16:31 | 18:35 | 20:35 | 08:25 | 08:40 | 08:05 | 10:32 | 12:35 | 14:30 | 16:30 | 20:55 |
| 18 | Schd: | 8:00 | 9:00 | 9:30 | 10:30 | 11:30 | 12:30 | 14:30 | 16:30 | 18:30 | 20:30 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 |
| 18 | Diff: | 5 | 5 | 7 | 5 | 2 | 4 | 3 | 1 | 5 | 5 | 25 | 40 | 5 | 2 | 5 | 0 | 0 | 25 |
| 19 | Act: | 8:26 | 9:02 | 9:35 | 10:30 | 11:32 | 12:30 | 14:30 | 16:55 | 18:37 | 20:20 | 08:35 | 08:33 | 08:28 | 10:43 | 12:41 | 14:32 | 17:00 | 20:38 |
| 19 | Schd: | 8:00 | 9:00 | 9:30 | 10:30 | 11:30 | 12:30 | 14:30 | 16:30 | 18:30 | 20:30 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 |
| 19 | Diff: | 26 | 2 | 5 | 0 | 2 | 0 | 0 | 25 | 7 | -10 | 35 | 33 | 28 | 13 | 11 | 2 | 30 | 8 |
| 20 | Act: | 7:38 | 8:35 | 9:05 | 10:00 | 11:00 | 12:00 | 14:00 | 16:00 | 18:03 | 19:55 | 08:00 | 07:47 | 08:00 | 10:13 | 12:08 | 14:19 | 16:15 | 20:20 |
| 20 | Schd: | 7:30 | 8:30 | 9:00 | 10:00 | 11:00 | 12:00 | 14:00 | 16:00 | 18:00 | 20:00 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 |
| 20 | Diff: | 8 | 5 | 5 | 0 | 0 | 0 | 0 | 0 | 3 | -5 | 30 | 17 | 30 | 13 | 8 | 19 | 15 | 20 |
| 21 | Act: | 8:12 | 8:44 | 9:17 | 10:16 | 11:15 | 12:17 | 14:16 | 16:15 | 18:35 | 20:00 | 08:20 | 08:15 | 08:00 | 10:02 | 12:06 | 14:00 | 16:05 | 20:40 |
| 21 | Schd: | 7:45 | 8:45 | 9:15 | 10:15 | 11:15 | 12:15 | 14:15 | 16:15 | 18:15 | 20:15 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 |
| 21 | Diff: | 27 | -1 | 2 | 1 | 0 | 2 | 1 | 0 | 20 | -15 | 35 | 30 | 15 | -13 | 9 | -15 | -10 | 25 |

Table 4-3
Blood Specimen PK Times

Blank = Not Obtained

| Subj | Date | Time | Day 5 | Day 6 | Day 7 | Day 7 | Day 7 | Day 7 | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 | Day 14 | Day 14 | Day 14 |
|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|
| | | | PRE | Pre | Pre | 2hr | 4hr | 6hr | 8hr | 12hr | Pre | Pre | Pre | Pre | Pre | 2hr | 4hr |
| 01 | Act: | 07:55 | 07:49 | 07:56 | 09:50 | 11:52 | 13:58 | 15:51 | 20:05 | 08:03 | 07:55 | 07:51 | 07:58 | 07:40 | 07:58 | 09:55 | 12:00 |
| 01 | Schd: | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 |
| 01 | Diff: | 25 | 19 | 26 | -10 | -8 | -2 | -9 | 5 | 33 | 25 | 21 | 28 | 15 | 28 | -5 | 0 |
| 02 | Act: | 08:05 | 08:20 | 08:18 | 10:02 | 12:05 | 14:20 | 16:07 | 20:25 | 08:10 | 08:17 | 08:16 | 08:20 | 08:05 | 08:09 | 10:08 | 12:10 |
| 02 | Schd: | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 |
| 02 | Diff: | 20 | 35 | 33 | -13 | -10 | 5 | -8 | 10 | 25 | 32 | 31 | 35 | 20 | 24 | -7 | -5 |
| 03 | Act: | 08:42 | 08:40 | 08:38 | 10:45 | 12:43 | 14:42 | 16:40 | 20:55 | 08:45 | 08:53 | 08:49 | 08:55 | 08:25 | 08:34 | 10:45 | 12:43 |
| 03 | Schd: | 8:20 | 8:20 | 8:20 | 10:50 | 12:50 | 14:50 | 16:50 | 20:50 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 10:50 | 12:50 |
| 03 | Diff: | 22 | 20 | 18 | -5 | -7 | -8 | -10 | 5 | 25 | 33 | 29 | 35 | 5 | 14 | -5 | -7 |
| 04 | Act: | 08:45 | 08:40 | 08:40 | 10:45 | 12:45 | 14:45 | 16:45 | 20:46 | 08:40 | 08:40 | 08:50 | 08:47 | 08:43 | 08:41 | 10:40 | 12:40 |
| 04 | Schd: | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 |
| 04 | Diff: | 45 | 40 | 40 | 15 | 15 | 15 | 15 | 16 | 40 | 40 | 50 | 47 | 43 | 41 | 10 | 10 |
| 05 | Act: | 08:25 | 08:20 | 08:25 | 10:25 | 12:25 | 14:25 | 16:21 | 20:25 | 08:29 | 08:25 | 08:29 | 08:20 | 08:25 | 08:16 | 10:25 | 12:25 |
| 05 | Schd: | 20:30 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 |
| 05 | Diff: | -725 | 20 | 25 | -5 | -5 | -5 | -9 | -5 | 29 | 25 | 29 | 20 | 25 | 16 | -5 | -5 |
| 06 | Act: | 08:55 | 08:50 | 09:10 | 11:10 | 13:15 | 15:10 | 17:10 | 21:20 | 08:51 | 09:10 | 08:59 | 08:48 | 08:48 | 08:38 | 10:50 | 12:50 |
| 06 | Schd: | 8:20 | 8:20 | 8:20 | 10:50 | 12:50 | 14:50 | 16:50 | 20:50 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 10:50 | 12:50 |
| 06 | Diff: | 35 | 30 | 50 | 20 | 25 | 20 | 20 | 30 | 31 | 50 | 39 | 28 | 26 | 18 | 0 | 0 |
| 07 | Act: | 09:00 | 08:54 | 08:54 | 11:10 | 13:04 | 15:02 | 17:03 | 21:30 | 09:10 | 09:00 | 09:25 | 08:45 | 09:10 | 09:14 | 11:07 | 13:07 |
| 07 | Schd: | 9:00 | 9:00 | 9:00 | 11:30 | 13:30 | 15:30 | 17:30 | 21:30 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 11:30 | 14:30 |
| 07 | Diff: | 0 | -6 | -6 | -20 | -26 | -28 | -27 | 0 | 10 | 0 | 25 | -15 | 10 | 14 | -23 | -83 |
| 08 | Act: | 08:03 | 08:07 | 07:55 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 08:03 | 07:55 | 08:05 | | | | | |
| 08 | Schd: | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 |
| 08 | Diff: | 33 | 37 | 25 | 0 | 0 | 0 | 0 | 0 | 33 | 25 | 35 | | | | | |
| 09 | Act: | 08:24 | 08:15 | 08:15 | 10:20 | 12:20 | 14:15 | 16:20 | 20:30 | 08:18 | 08:20 | 08:30 | 08:13 | 08:17 | 08:20 | 10:35 | 12:34 |
| 09 | Schd: | 7:50 | 7:50 | 7:50 | 10:20 | 12:20 | 14:20 | 16:20 | 20:20 | 7:50 | 7:50 | 7:50 | 7:50 | 7:50 | 7:50 | 10:20 | 12:20 |
| 09 | Diff: | 34 | 25 | 25 | 0 | 0 | -5 | 0 | 10 | 28 | 30 | 40 | 23 | 27 | 30 | 15 | 14 |
| 10 | Act: | 08:38 | 08:38 | 08:35 | 10:42 | 12:45 | 14:45 | 16:42 | 22:10 | 08:45 | 08:45 | 09:05 | 08:30 | 08:55 | 08:36 | 10:34 | 12:45 |
| 10 | Schd: | 8:10 | 8:10 | 8:10 | 10:40 | 12:40 | 14:40 | 16:40 | 20:40 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 10:40 | 12:40 |
| 10 | Diff: | 28 | 28 | 25 | 2 | 5 | 5 | 2 | 90 | 35 | 35 | 55 | 20 | 45 | 26 | -6 | 5 |
| 11 | Act: | 09:30 | 09:35 | 09:15 | 11:20 | 13:25 | 15:10 | 17:10 | 21:24 | 09:38 | 09:14 | 09:30 | 09:59 | 09:20 | 09:00 | 11:30 | 13:31 |
| 11 | Schd: | 8:50 | 8:50 | 8:50 | 11:20 | 13:20 | 15:20 | 17:20 | 21:20 | 8:50 | 8:50 | 8:50 | 8:50 | 8:50 | 8:50 | 11:20 | 13:20 |
| 11 | Diff: | 40 | 45 | 25 | 0 | 5 | -10 | -10 | 4 | 48 | 24 | 40 | 69 | 30 | 10 | 10 | 11 |

Table 4-4
Blood Specimen PK Times

Blank = Not Obtained

| Subj | Date | Day 5 | Day 6 | Day 7 | Day 7 | Day 7 | Day 7 | Day 7 | Day 7 | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 | Day 14 | Day 14 | Day 14 |
|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|
| Time | PRE | Pre | Pre | Pre | 2hr | 4hr | 6hr | 8hr | 12hr | Pre | Pre | Pre | Pre | Pre | Pre | Pre | 2hr | 4hr |
| 12 | Act: | 08:13 | 08:20 | 08:18 | 10:12 | 12:13 | 14:13 | 16:15 | 22:20 | 08:12 | 08:17 | 08:25 | 08:20 | 08:30 | 08:20 | 08:15 | 10:25 | 12:30 |
| 12 | Schd: | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 |
| 12 | Diff: | 28 | 35 | 33 | -3 | -2 | -2 | 0 | 125 | 27 | 32 | 40 | 35 | 45 | 35 | 30 | 10 | 15 |
| 13 | Act: | 08:56 | 08:55 | 09:00 | 11:20 | 13:15 | 15:15 | 17:12 | 21:17 | 09:00 | 09:23 | 10:05 | 09:05 | 09:00 | 08:59 | 08:55 | 11:10 | 13:00 |
| 13 | Schd: | 8:30 | 8:30 | 8:30 | 11:00 | 13:00 | 15:00 | 17:00 | 21:00 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 11:00 | 13:00 |
| 13 | Diff: | 26 | 25 | 30 | 20 | 15 | 15 | 12 | 17 | 30 | 53 | 95 | 35 | 30 | 29 | 25 | 10 | 0 |
| 14 | Act: | 08:10 | 08:15 | 08:24 | 10:24 | 12:16 | 14:27 | 16:19 | 20:43 | 08:28 | 08:15 | 09:05 | 08:17 | 08:15 | 08:20 | 08:20 | 10:28 | 12:20 |
| 14 | Schd: | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 |
| 14 | Diff: | 10 | 15 | 24 | -6 | -14 | -3 | -11 | 13 | 28 | 15 | 65 | 17 | 15 | 20 | 20 | -2 | -10 |
| 15 | Act: | 08:35 | 08:38 | 08:44 | 11:00 | 12:55 | 15:00 | 16:35 | 20:58 | 08:45 | 08:50 | 09:25 | 08:38 | 08:45 | 08:40 | 08:28 | 10:41 | 12:40 |
| 15 | Schd: | 8:10 | 8:10 | 8:10 | 10:40 | 12:40 | 14:40 | 16:40 | 20:40 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 10:40 | 12:40 |
| 15 | Diff: | 25 | 28 | 34 | 20 | 15 | 20 | -5 | 18 | 35 | 40 | 75 | 28 | 35 | 30 | 18 | 1 | 0 |
| 16 | Act: | 07:36 | 07:55 | 08:02 | 10:06 | 12:02 | 14:08 | 16:02 | 20:05 | 08:10 | 07:45 | 08:35 | 07:55 | 07:50 | 07:58 | 08:00 | 10:05 | 12:00 |
| 16 | Schd: | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 |
| 16 | Diff: | 6 | 25 | 32 | 6 | 2 | 8 | 2 | 5 | 40 | 15 | 65 | 25 | 20 | 28 | 30 | 5 | 0 |
| 17 | Act: | | | | | | | | | | | | | | | | | |
| 17 | Schd: | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 |
| 17 | Diff: | | | | | | | | | | | | | | | | | |
| 18 | Act: | 08:15 | 08:11 | 07:45 | 10:33 | 12:34 | 14:30 | 16:32 | 20:28 | 08:20 | 08:35 | 07:45 | 07:58 | 08:02 | 08:25 | 08:20 | 10:30 | 12:35 |
| 18 | Schd: | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 |
| 18 | Diff: | 15 | 11 | -15 | 3 | 4 | 0 | 2 | -2 | 20 | 35 | -15 | -2 | 2 | 25 | 20 | 0 | 5 |
| 19 | Act: | 08:23 | 08:02 | 08:25 | 12:11 | 12:35 | 14:35 | 16:25 | 20:45 | 08:32 | 08:30 | 08:25 | 08:20 | 08:20 | 08:23 | 08:10 | 10:32 | 12:34 |
| 19 | Schd: | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 |
| 19 | Diff: | 23 | 2 | 25 | 101 | 5 | 5 | -5 | 15 | 32 | 30 | 25 | 20 | 20 | 23 | 10 | 2 | 4 |
| 20 | Act: | 08:00 | 07:58 | 07:56 | 09:58 | 12:08 | 14:07 | 16:10 | 20:05 | 07:59 | 08:10 | 08:12 | 07:58 | 07:55 | 07:55 | 07:50 | 10:10 | 12:03 |
| 20 | Schd: | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 |
| 20 | Diff: | 30 | 28 | 26 | -2 | 8 | 7 | 10 | 5 | 29 | 40 | 42 | 28 | 25 | 25 | 20 | 10 | 3 |
| 21 | Act: | 07:50 | 07:40 | 07:56 | 09:55 | 12:00 | 13:58 | 15:56 | 20:00 | 08:01 | 08:10 | 08:28 | 08:10 | 07:50 | 07:40 | 07:47 | 10:10 | 12:06 |
| 21 | Schd: | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 |
| 21 | Diff: | 5 | -5 | 11 | -20 | -15 | -17 | -19 | -15 | 16 | 25 | 43 | 25 | 5 | -5 | 2 | -5 | -9 |

Blank = Not Obtained

| Subj | Date Time | Day 14 | | Day 14 | Day 15 | | Day 16 | Day 17 | | Day 18 | Day 19 | | Day 20 | Day 21 | | Day 21 | Day 21 | | Day 21 | Day 21 | Day 21 | Day 21 | Day 21 | Day 21 | Day 21 |
|------|--------------|--------|-------|--------|--------|-------|--------|--------|-------|--------|--------|-------|--------|--------|-------|--------|--------|-----|--------|--------|--------|--------|--------|--------|--------|
| | | 6hr | 8hr | 12hr | Pre | Pre | Pre | Pre | Pre | Pre | Pre | Pre | Pre | Pre | Pre | 2hr | 4hr | 6hr | 8hr | 12hr | Pre | Pre | Pre | Pre | Pre |
| 01 | Act: | 14:00 | 16:07 | 20:10 | 07:55 | 07:50 | 07:53 | 07:40 | 07:50 | 07:57 | 07:56 | 10:00 | 12:00 | 14:00 | 16:00 | 19:40 | 07:50 | | | | | | | | |
| 01 | Schd: | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | | | | | | | | |
| 01 | Diff: | 0 | 7 | 10 | 25 | 20 | 23 | 10 | 20 | 27 | 26 | 0 | 0 | 0 | 0 | -20 | 20 | | | | | | | | |
| 02 | Act: | 14:23 | 16:20 | 20:35 | 08:13 | 08:13 | 08:20 | 08:20 | 08:05 | 08:10 | 08:12 | 10:15 | 12:15 | 14:15 | 16:15 | 20:00 | 08:10 | | | | | | | | |
| 02 | Schd: | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 | 7:45 | | | | | | | | |
| 02 | Diff: | 8 | 5 | 20 | 28 | 28 | 35 | 35 | 20 | 25 | 27 | 0 | 0 | 0 | 0 | -15 | 25 | | | | | | | | |
| 03 | Act: | 14:56 | 16:43 | 20:55 | 08:52 | 08:47 | 08:51 | 08:50 | 08:13 | 08:50 | 08:50 | 10:53 | 12:53 | 14:53 | 16:59 | 21:07 | 09:15 | | | | | | | | |
| 03 | Schd: | 14:50 | 16:50 | 20:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 10:50 | 12:50 | 14:50 | 16:50 | 20:50 | 8:20 | | | | | | | | |
| 03 | Diff: | 6 | -7 | 35 | 32 | 27 | 31 | 30 | -7 | 30 | 30 | 3 | 3 | 3 | 9 | 17 | 55 | | | | | | | | |
| 04 | Act: | 14:40 | 16:40 | 20:40 | 08:35 | 08:44 | 08:45 | 10:05 | 08:57 | 08:45 | 08:39 | 10:40 | 12:40 | 14:55 | 16:45 | 20:42 | 08:45 | | | | | | | | |
| 04 | Schd: | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | | | | | | | | |
| 04 | Diff: | 10 | 10 | 10 | 35 | 44 | 45 | 125 | 57 | 45 | 39 | 10 | 10 | 25 | 15 | 12 | 45 | | | | | | | | |
| 05 | Act: | 14:25 | 16:31 | 20:30 | 08:20 | 08:33 | 09:15 | 09:43 | 08:22 | 08:25 | 08:17 | 12:25 | 12:25 | 14:25 | 16:25 | 20:20 | 08:24 | | | | | | | | |
| 05 | Schd: | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 12:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | | | | | | | | |
| 05 | Diff: | -5 | 1 | 0 | 20 | 33 | 75 | 103 | 22 | 25 | 17 | -5 | -5 | -5 | -5 | -10 | 24 | | | | | | | | |
| 06 | Act: | 14:58 | 16:57 | 20:47 | 08:39 | 09:00 | 08:59 | 08:39 | 08:55 | 08:35 | 08:50 | 12:55 | 12:55 | 14:55 | 16:55 | 21:43 | 08:56 | | | | | | | | |
| 06 | Schd: | 14:50 | 16:50 | 20:50 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 10:50 | 12:50 | 14:50 | 16:50 | 20:50 | 8:20 | | | | | | | | |
| 06 | Diff: | 8 | 7 | -3 | 19 | 40 | 39 | 19 | 35 | 15 | 30 | 125 | 5 | 5 | 5 | 53 | 36 | | | | | | | | |
| 07 | Act: | 15:07 | 17:10 | 21:00 | 10:10 | 09:07 | 09:30 | 09:05 | 09:41 | 09:10 | 09:12 | 11:20 | 13:15 | 14:22 | 16:47 | 21:40 | 09:03 | | | | | | | | |
| 07 | Schd: | 15:30 | 17:30 | 21:30 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 11:30 | 13:30 | 15:30 | 17:30 | 21:30 | 9:00 | | | | | | | | |
| 07 | Diff: | -23 | -20 | -30 | 70 | 7 | 30 | 5 | 41 | 10 | 12 | -10 | -15 | -68 | -43 | 10 | 3 | | | | | | | | |
| 08 | Act: | | | | | | | | | | | | | | | | | | | | | | | | |
| 08 | Schd: | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | | | | | | | | |
| 08 | Diff: | | | | | | | | | | | | | | | | | | | | | | | | |

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Blank = Not Obtained

| | Date | Day 14 | Day 14 | Day 14 | Day 15 | Day 16 | Day 17 | Day 18 | Day 19 | Day 20 | Day 21 | Day 21 | Day 21 | Day 21 | Day 21 | Day 21 | Day 21 | Day 22 |
|------|-------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Subj | Time | 6hr | 8hr | 12hr | Pre | Pre | Pre | Pre | Pre | Pre | Pre | 2hr | 4hr | 6hr | 8hr | 12hr | Pre | Pre |
| 12 | Act: | 14:30 | 16:25 | 20:20 | 08:22 | 09:10 | 08:15 | 08:14 | 08:05 | 08:13 | 08:00 | 10:13 | 12:16 | 14:22 | 16:58 | 20:22 | 08:13 | 08:13 |
| 12 | Schd: | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 |
| 12 | Diff: | 15 | 10 | 5 | 37 | 85 | 30 | 29 | 20 | 28 | 15 | -2 | 1 | 7 | 43 | 7 | 28 | 28 |
| 13 | Act: | 15:10 | 17:04 | 21:12 | 08:52 | 08:10 | 09:35 | 09:30 | 08:57 | 09:12 | 09:05 | 11:20 | 13:15 | 15:19 | 17:10 | 21:12 | 08:50 | 08:50 |
| 13 | Schd: | 15:00 | 17:00 | 21:00 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 11:00 | 13:00 | 15:00 | 17:00 | 21:00 | 8:30 | 8:30 |
| 13 | Diff: | 10 | 4 | 12 | 22 | -20 | 65 | 60 | 27 | 42 | 35 | 20 | 15 | 19 | 10 | 12 | 20 | 20 |
| 14 | Act: | 14:20 | 16:20 | 20:23 | 08:25 | 08:40 | 08:14 | 08:22 | 08:34 | 08:16 | 08:50 | 11:59 | 12:57 | 14:55 | 16:46 | 21:05 | 08:18 | 08:18 |
| 14 | Schd: | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 |
| 14 | Diff: | -10 | -10 | -7 | 25 | 40 | 14 | 22 | 34 | 16 | 50 | 89 | 27 | 25 | 16 | 35 | 18 | 18 |
| 15 | Act: | 14:42 | 16:40 | 21:00 | 08:36 | 07:45 | 09:04 | 08:55 | 08:35 | 08:45 | 08:37 | 10:45 | 12:45 | 14:45 | 16:45 | 20:47 | 08:37 | 08:37 |
| 15 | Schd: | 14:40 | 16:40 | 20:40 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 10:40 | 12:40 | 14:40 | 16:40 | 20:40 | 8:10 | 8:10 |
| 15 | Diff: | 2 | 0 | 20 | 26 | -25 | 54 | 45 | 25 | 35 | 27 | 5 | 5 | 5 | 5 | 7 | 27 | 27 |
| 16 | Act: | 14:00 | 16:00 | 19:55 | 07:55 | 07:45 | 08:10 | 08:04 | 08:04 | 07:58 | 07:56 | 10:10 | 12:06 | 14:02 | 16:05 | 20:01 | 07:58 | 07:58 |
| 16 | Schd: | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 |
| 16 | Diff: | 0 | 0 | -5 | 25 | 15 | 40 | 34 | 34 | 28 | 26 | 10 | 6 | 2 | 5 | 1 | 28 | 28 |
| 17 | Act: | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 |
| 17 | Schd: | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 |
| 17 | Diff: | | | | | | | | | | | | | | | | | |
| 18 | Act: | 14:35 | 16:35 | 20:30 | 08:20 | 08:45 | 08:55 | 08:17 | 08:25 | 08:20 | 08:15 | 10:32 | 12:30 | 14:30 | 16:30 | 20:50 | 08:30 | 08:30 |
| 18 | Schd: | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 |
| 18 | Diff: | 5 | 5 | 0 | 20 | 45 | 55 | 17 | 25 | 20 | 15 | 2 | 0 | 0 | 0 | 20 | 30 | 30 |
| 19 | Act: | 14:34 | 16:33 | 20:25 | 08:20 | 08:23 | 08:10 | 08:20 | 08:25 | 07:30 | 08:04 | 10:30 | 12:30 | 14:30 | 16:36 | 20:49 | 08:20 | 08:20 |
| 19 | Schd: | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 10:30 | 12:30 | 14:30 | 16:30 | 20:30 | 8:00 | 8:00 |
| 19 | Diff: | 4 | 3 | -5 | 20 | 23 | 10 | 20 | 25 | -30 | 4 | 0 | 0 | 0 | 6 | 19 | 20 | 20 |
| 20 | Act: | 14:00 | 16:02 | 20:15 | 07:55 | 07:36 | 07:37 | 07:58 | 07:55 | 07:58 | 07:55 | 10:02 | 12:05 | 13:55 | 15:50 | 20:10 | 07:50 | 07:50 |
| 20 | Schd: | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 7:30 | 7:30 |
| 20 | Diff: | 0 | 2 | 15 | 25 | 6 | 7 | 28 | 25 | 28 | 25 | 2 | 5 | -5 | -10 | 10 | 20 | 20 |
| 21 | Act: | 14:05 | 16:08 | 20:20 | 07:50 | 08:00 | 07:57 | 08:00 | 07:55 | 07:58 | 07:45 | 10:00 | 12:00 | 14:00 | 16:00 | 20:00 | 08:10 | 08:10 |
| 21 | Schd: | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 10:15 | 12:15 | 14:15 | 16:15 | 20:15 | 7:45 | 7:45 |
| 21 | Diff: | -10 | -7 | 5 | 5 | 15 | 12 | 15 | 10 | 13 | 0 | -15 | -15 | -15 | -15 | -15 | 25 | 25 |

Blank = Not Obtained

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Dec. 17, 1998

Table 4-9
Blood Specimen PK Times

Blank = Not Obtained

| Subj | Date | Day 44 | Day 45 | Day 48 | Day 51 | Day 54 | Day 57 | Day 72 | Day 180 |
|------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| Time | AM | AM | AM | AM | AM | AM | AM | AM | AM |
| 01 | Act: | 08:45 | 08:38 | 09:18 | 08:50 | 08:33 | 08:50 | 09:55 | 10:00 |
| 01 | Schd: | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 |
| 01 | Diff: | 75 | 68 | 108 | 80 | 63 | 80 | 145 | 150 |
| 02 | Act: | | | | | | | | |
| 02 | Schd: | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 |
| 02 | Diff: | | | | | | | | |
| 03 | Act: | 15:45 | 09:57 | 09:00 | 08:10 | 08:10 | 08:28 | 13:54 | 09:00 |
| 03 | Schd: | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 |
| 03 | Diff: | 445 | 97 | 40 | -10 | -10 | 8 | 334 | 40 |
| 04 | Act: | | | | | | | | |
| 04 | Schd: | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 |
| 04 | Diff: | | | | | | | | |
| 05 | Act: | | | | | | | | |
| 05 | Schd: | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 |
| 05 | Diff: | | | | | | | | |
| 06 | Act: | 09:50 | 09:25 | 08:48 | 08:55 | 08:55 | 08:40 | 08:55 | 08:55 |
| 06 | Schd: | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 | 8:20 |
| 06 | Diff: | 90 | 65 | 28 | 35 | 35 | 20 | 35 | 35 |
| 07 | Act: | | | | 12:00 | 23:40 | 19:00 | 18:20 | 00:44 |
| 07 | Schd: | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 | 9:00 |
| 07 | Diff: | | | | 180 | 880 | 600 | 560 | -496 |
| 08 | Act: | | | | | | | | |
| 08 | Schd: | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 |
| 08 | Diff: | | | | | | | | |
| 09 | Act: | 11:30 | | 10:25 | 12:20 | 14:20 | 15:05 | 11:32 | 15:30 |
| 09 | Schd: | 7:50 | 7:50 | 7:50 | 7:50 | 7:50 | 7:50 | 7:50 | 7:50 |
| 09 | Diff: | 220 | 155 | 155 | 270 | 390 | 435 | 222 | 460 |
| 10 | Act: | 15:20 | | | 10:30 | 13:35 | | | |
| 10 | Schd: | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 |
| 10 | Diff: | 430 | | | 140 | 325 | | | |
| 11 | Act: | 09:40 | 14:03 | | | | | | |
| 11 | Schd: | 8:50 | 8:50 | 8:50 | 8:50 | 8:50 | 8:50 | 8:50 | 8:50 |
| 11 | Diff: | 50 | 313 | | | | | | |

Table 4-10
Blood Specimen PK Times

Blank = Not Obtained

| Subj | Date Time | Day 44 AM | Day 45 AM | Day 48 AM | Day 51 AM | Day 54 AM | Day 57 AM | Day 72 AM | Day 180 AM |
|------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| 12 | Act: | 08:34 | 09:05 | 08:22 | 08:40 | 08:28 | 08:15 | 08:56 | 09:10 |
| 12 | Schd: | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 |
| 12 | Diff: | 49 | 80 | 37 | 55 | 43 | 30 | 71 | 85 |
| 13 | Act: | 09:40 | 09:42 | 11:55 | 10:57 | 17:00 | 13:09 | 13:55 | 11:50 |
| 13 | Schd: | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 | 8:30 |
| 13 | Diff: | 70 | 72 | 205 | 147 | 510 | 279 | 325 | 200 |
| 14 | Act: | | | | | | | | |
| 14 | Schd: | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 |
| 14 | Diff: | | | | | | | | |
| 15 | Act: | 13:55 | 16:18 | 10:30 | 10:40 | 11:45 | 14:07 | 10:05 | 11:05 |
| 15 | Schd: | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 | 8:10 |
| 15 | Diff: | 345 | 488 | 140 | 150 | 215 | 357 | 115 | 175 |
| 16 | Act: | 09:15 | | | | | | | 09:30 |
| 16 | Schd: | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 |
| 16 | Diff: | 105 | | | | | | | 120 |
| 17 | Act: | | 18:00 | 09:42 | 08:45 | 15:15 | 17:25 | 11:40 | |
| 17 | Schd: | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 |
| 17 | Diff: | | 600 | 102 | 45 | 435 | 565 | 220 | |
| 18 | Act: | | 18:00 | 09:42 | 8:45* | 15:15 | 17:25* | 11:40 | |
| 18 | Schd: | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 |
| 18 | Diff: | | 600 | 102 | 1485 | 435 | 2005 | 220 | |
| 19 | Act: | 08:40 | 09:07 | 09:50 | 09:45 | 09:30 | 09:15 | 09:30 | |
| 19 | Schd: | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 | 8:00 |
| 19 | Diff: | 40 | 67 | 110 | 105 | 90 | 75 | 90 | |
| 20 | Act: | 08:35 | 10:58 | 11:20 | 13:30 | | | | |
| 20 | Schd: | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 | 7:30 |
| 20 | Diff: | 65 | 208 | 230 | 360 | | | | |
| 21 | Act: | 08:56 | 10:50 | 10:17 | 14:00 | 09:45 | 09:00 | 09:05 | |
| 21 | Schd: | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 | 7:45 |
| 21 | Diff: | 71 | 185 | 152 | 375 | 120 | 75 | 80 | |

* Blood drawn on following day

Table 5

| Subject Number | Drug Screen | Chest X-Ray | Pulmonary Function | | TSH | HIV | HBsAG | HbC Serology | HbCAB |
|---------------------------|-------------|-------------|--------------------|--------|--------|--------|--------|--------------|--------|
| Time--> | Screen | Screen | Screen | Day 42 | µIU/ml | Screen | Screen | Screen | Screen |
| 01 | - | - | Normal | Normal | 2.10 | - | - | - | - |
| 02 | - | - | Normal | | 0.67 | - | - | - | - |
| 03 | - | - | Normal | Normal | 1.70 | - | - | - | - |
| 04 | - | - | Normal | Normal | 0.11 | - | - | - | - |
| 05 | - | - | Normal | | 0.70 | - | - | - | - |
| 06 | - | - | Normal | Normal | 0.44 | - | - | - | - |
| 07 | - | - | Normal | Normal | 0.90 | - | - | - | - |
| 08 | - | - | Normal | | 0.60 | - | - | - | - |
| 09 | - | - | Normal | Normal | 1.70 | - | - | - | - |
| 10 | - | - | Normal | Normal | 0.80 | - | - | - | - |
| 11 | - | - | Normal | Normal | 1.90 | - | - | - | - |
| 12 | - | - | Normal | Normal | 1.45 | - | - | - | - |
| 13 | - | - | Normal | Normal | | - | - | - | - |
| 14 | - | - | Normal | | 1.27 | - | - | - | - |
| 15 | - | - | Normal | Normal | 2.01 | - | - | - | - |
| 16 | - | - | Normal | Normal | 0.29 | - | - | - | + |
| 17 | - | - | Normal | | 4.08 | - | - | + | - |
| 18 | - | - | Normal | Normal | 1.40 | - | - | - | - |
| 19 | - | - | Normal | | 0.70 | - | - | - | - |
| 20 | - | - | Normal | Normal | 1.67 | - | - | - | - |
| 21 | - | - | Normal | Normal | 2.36 | - | - | - | - |
| Blank Cell = Not Obtained | | | | | | | | | |
| Average | | | | | 1.34 | | | | |
| Std Dev | | | | | 0.92 | | | | |
| Max | | | | | 4.08 | | | | |
| Min | | | | | 0.11 | | | | |

Units: mmHg

Table 6a-1
Vital Signs: Systolic BP

Blank = Not Obtained

| Subj \ Day | 00 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|------------|-------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 01 | | 122 | 112 | 112 | 106 | 108 | 116 | 106 | 114 | 118 | 123 | 116 | 134 | 128 | 131 | 126 | 118 |
| 02 | 132 | 128 | 117 | 122 | 125 | 132 | 112 | 116 | 136 | 137 | 129 | 124 | 130 | 128 | 149 | 132 | 134 |
| 03 | 132 | 100 | 116 | 107 | 92 | 100 | 101 | 96 | 96 | 95 | 95 | 95 | 118 | 94 | 130 | 106 | 90 |
| 04 | 112 | 128 | 112 | 108 | 118 | 124 | 138 | 118 | 123 | 122 | 122 | 132 | 132 | 126 | 140 | 126 | 118 |
| 05 | 139 | 114 | 102 | 114 | 120 | 118 | 104 | 98 | 114 | 108 | 113 | 108 | 110 | 114 | 110 | 104 | 114 |
| 06 | 124 | 148 | 108 | 127 | 122 | 122 | 122 | 135 | 116 | 114 | 125 | 124 | 124 | 122 | 133 | 126 | 114 |
| 07 | 154 | 123 | 144 | 118 | 132 | 134 | 136 | 146 | 134 | 133 | 137 | 128 | 140 | 139 | 128 | 158 | 140 |
| 08 | 122 | 134 | 118 | 106 | 104 | 114 | 108 | 112 | 126 | 115 | 106 | | | | | | |
| 09 | 120 | 126 | 128 | 120 | 128 | 126 | 126 | 112 | 118 | 116 | 108 | 104 | 122 | 122 | 112 | 122 | 108 |
| 10 | 128 | 124 | 122 | 114 | 118 | 124 | 124 | 136 | 97 | 125 | 114 | 138 | 124 | 119 | 122 | 127 | 128 |
| 11 | 130 | 116 | 106 | 98 | 97 | 97 | 106 | 110 | 102 | 93 | 89 | 104 | 100 | 90 | 108 | 108 | 113 |
| 12 | 134 | 104 | 132 | 118 | 116 | 112 | 115 | 121 | 122 | 122 | 116 | 120 | 134 | 129 | 128 | 102 | 130 |
| 13 | 132 | 112 | 115 | 109 | 108 | 122 | 108 | 120 | 118 | 106 | 92 | 104 | 110 | 108 | 114 | 110 | 116 |
| 14 | 112 | 106 | 104 | 114 | 116 | 118 | 122 | 118 | 124 | 107 | 100 | 116 | 128 | 109 | 100 | 108 | 102 |
| 15 | 140 | 110 | 117 | 116 | 106 | 112 | 122 | 114 | 116 | 107 | 110 | 122 | 104 | 114 | 102 | 117 | 106 |
| 16 | 117 | 92 | 104 | 90 | 90 | 105 | 102 | 96 | 102 | 108 | 94 | 100 | 106 | 104 | 105 | 102 | 98 |
| 17 | 100 | 128 | 119 | | | | | | | | | | | | | | |
| 18 | | 108 | 114 | 108 | 116 | 106 | 106 | 124 | 94 | 112 | 103 | 106 | 104 | 96 | 110 | 107 | 105 |
| 19 | 131 | 108 | 128 | 134 | 110 | 115 | 96 | 120 | 125 | 104 | 118 | 96 | 118 | 86 | 127 | 120 | 98 |
| 20 | 125 | 122 | 125 | 132 | 116 | 122 | 122 | 110 | 122 | 118 | 114 | 104 | 114 | 118 | 126 | 110 | 112 |
| 21 | 112 | 95 | 83 | 90 | 94 | 82 | 94 | 105 | 106 | 92 | 96 | 99 | 102 | 100 | 92 | 90 | 80 |
| Summary: | Systolic BP, mmHg | | | | | | | | | | | | | | | | |
| Average | 126.1 | 116.6 | 115.5 | 112.9 | 111.7 | 114.7 | 114.0 | 115.7 | 115.3 | 112.6 | 110.2 | 112.6 | 118.6 | 112.9 | 119.3 | 115.8 | 111.8 |
| Std Dev | 12.4 | 13.7 | 12.7 | 11.8 | 11.9 | 12.5 | 12.4 | 13.1 | 12.2 | 12.1 | 13.3 | 12.9 | 12.4 | 14.9 | 14.9 | 15.1 | 15.0 |
| Max | 154 | 148 | 144 | 134 | 132 | 134 | 138 | 146 | 136 | 137 | 137 | 138 | 140 | 139 | 149 | 158 | 140 |
| Min | 100 | 92 | 83 | 90 | 90 | 82 | 94 | 96 | 94 | 92 | 89 | 95 | 100 | 86 | 92 | 90 | 80 |

Units: mmHg

Table 6a-2
Vital Signs: Systolic BP

Blank = Not Obtained

| Subj \ Day | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 01 | 132 | 122 | 120 | | | 134 | 136 | 120 | 118 | 138 | 120 | 130 | 126 | 120 | 130 | 128 | 114 |
| 02 | 122 | 112 | 116 | 120 | 134 | 122 | 113 | 136 | 145 | 138 | 142 | 138 | 124 | 136 | 134 | 142 | |
| 03 | 92 | 92 | 90 | 90 | 90 | 96 | 136 | 98 | 90 | 106 | 106 | 91 | 116 | 106 | 98 | 98 | 96 |
| 04 | 132 | 123 | 110 | 134 | 90 | 140 | 134 | 132 | 124 | 128 | 122 | 132 | 117 | 124 | 132 | 132 | 124 |
| 05 | 118 | 108 | 109 | 107 | 110 | 122 | 113 | 123 | 120 | | 148 | 124 | | | | | |
| 06 | 108 | 118 | 120 | 122 | 130 | 114 | 124 | 120 | 133 | 116 | 112 | 140 | 122 | 128 | 134 | 132 | 123 |
| 07 | 128 | 148 | 126 | 136 | 164 | 140 | 138 | 136 | 139 | 144 | 135 | 126 | 122 | 126 | 120 | 120 | |
| 08 | | | | | | | | | | | | | | | | | |
| 09 | 108 | 110 | 118 | 116 | 124 | 108 | 132 | 125 | 116 | 114 | 127 | 116 | 140 | 120 | 125 | 116 | 110 |
| 10 | 120 | 136 | 132 | 119 | 112 | 116 | 125 | 112 | 122 | 135 | 152 | 120 | 132 | 126 | 132 | 124 | 108 |
| 11 | 98 | 110 | 114 | 127 | 106 | 128 | 110 | 110 | 124 | 116 | 127 | 124 | 130 | 140 | 128 | 126 | 113 |
| 12 | 100 | 126 | 130 | 124 | 112 | 116 | 116 | 116 | 120 | 134 | 122 | 142 | 135 | 112 | 118 | 132 | 143 |
| 13 | 114 | 112 | 124 | 107 | 116 | 122 | 122 | 114 | 120 | 122 | 112 | 124 | 122 | 116 | 113 | 124 | 146 |
| 14 | 122 | 118 | 116 | 118 | 118 | 138 | 135 | 114 | 118 | 123 | 119 | 126 | 114 | 136 | 131 | 124 | 136 |
| 15 | 98 | 110 | 114 | 116 | 116 | 127 | 143 | 122 | 128 | 130 | 134 | 110 | 133 | 102 | 136 | 124 | 138 |
| 16 | 92 | 98 | 110 | 110 | 106 | 104 | | 98 | 90 | 117 | 129 | 128 | 108 | | 116 | 134 | 118 |
| 17 | | | | | | | | | | | | | | | | | |
| 18 | 96 | 100 | 98 | 114 | 107 | 118 | | | 108 | 130 | 124 | | 142 | 137 | | 126 | 124 |
| 19 | 106 | 106 | 119 | 118 | 100 | 112 | 108 | 124 | 120 | 103 | 116 | 120 | 130 | 146 | 118 | 118 | 128 |
| 20 | 119 | 116 | 120 | 114 | 114 | 104 | 136 | | 116 | 112 | 125 | 124 | 120 | 124 | 124 | 115 | 117 |
| 21 | 86 | 103 | 105 | 91 | 96 | 103 | | | 97 | 117 | | 113 | 118 | | | 120 | 115 |
| Summary: | | | | | | | | | | | | | | | | | |
| Average | 110.1 | 114.1 | 115.3 | 115.7 | 113.6 | 119.2 | 126.3 | 118.8 | 118.3 | 123.5 | 126.2 | 123.8 | 125.1 | 124.9 | 124.3 | 124.2 | 122.1 |
| Std Dev | 14.3 | 13.3 | 10.3 | 12.1 | 17.4 | 13.1 | 11.4 | 11.3 | 14.4 | 11.7 | 12.3 | 11.9 | 9.2 | 12.3 | 10.1 | 9.5 | 13.6 |
| Max | 132 | 148 | 132 | 136 | 164 | 140 | 143 | 136 | 145 | 144 | 152 | 142 | 142 | 146 | 136 | 142 | 146 |
| Min | 86 | 92 | 90 | 90 | 90 | 96 | 108 | 98 | 90 | 103 | 106 | 91 | 108 | 102 | 98 | 98 | 96 |

Units: mmHg

Table 6a-3
Vital Signs: Systolic BP

Blank = Not Obtained

| Subj \ Day | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 48 | 51 | 54 | 57 | 72 |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 01 | 100 | 108 | 108 | 116 | 118 | 116 | 132 | 112 | 116 | 110 | 122 | 126 | 122 | 124 | 128 | 116 | 130 |
| 02 | 126 | 136 | | | | | | | | | | | | | | | |
| 03 | 94 | 108 | 114 | 110 | 102 | 112 | 100 | 106 | 98 | 98 | 116 | 124 | 106 | 96 | 114 | 113 | 106 |
| 04 | 134 | 132 | 134 | 118 | | | | | | | | | | | | | |
| 05 | | | | | | | | | | | | | | | | | |
| 06 | 130 | 134 | 132 | 124 | 116 | 125 | 120 | 130 | 114 | 130 | 115 | 132 | 134 | 124 | 120 | 132 | 122 |
| 07 | | 126 | 140 | 132 | 108 | 136 | 117 | | 142 | 121 | | | | 122 | 108 | 152 | 134 |
| 08 | | | | | | | | | | | | | | | | | |
| 09 | 112 | | 117 | 120 | 115 | 104 | 126 | 108 | 112 | 109 | 114 | 132 | 126 | 115 | 116 | 120 | 115 |
| 10 | 152 | 119 | 122 | 120 | 115 | 122 | 116 | 104 | 116 | 132 | 128 | 120 | | 130 | 124 | | |
| 11 | 138 | 116 | 130 | 119 | 134 | 125 | 134 | 108 | 94 | 112 | 104 | 118 | | | | | |
| 12 | 128 | 118 | 106 | 123 | 116 | 126 | 123 | 102 | 134 | 126 | 126 | 106 | 126 | 131 | 128 | 126 | 147 |
| 13 | 120 | 120 | 120 | 120 | 128 | 112 | 131 | 106 | 106 | 120 | 106 | 122 | 128 | 132 | 118 | 112 | 120 |
| 14 | 124 | 138 | 154 | 124 | 125 | 144 | 127 | | | | | | | | | | |
| 15 | 112 | 123 | 114 | 136 | 130 | 122 | 128 | 122 | 108 | 139 | 110 | 125 | 116 | 124 | 132 | 114 | 138 |
| 16 | 120 | 111 | 110 | 131 | 115 | 108 | 106 | 97 | 104 | 112 | 116 | | | | | | 114 |
| 17 | | | | | | | | | | | | | | | | | |
| 18 | 124 | 138 | | 120 | 126 | | 130 | 132 | 119 | 128 | | 122 | 138 | 112 | 134 | 134 | 136 |
| 19 | 114 | 119 | 126 | 112 | 123 | 124 | 131 | 119 | 128 | 98 | 122 | ND | 136 | 116 | 116 | 105 | 113 |
| 20 | 124 | 118 | | | | 130 | 118 | 119 | 92 | 116 | 121 | 126 | 124 | 112 | 132 | 108 | |
| 21 | 121 | 124 | 116 | | | 120 | 134 | 115 | 100 | 107 | 102 | 96 | 134 | 112 | 100 | 123 | 100 |
| Summary: | | | | | | | | | | | | | | | | | |
| Average | 121.9 | 122.8 | 122.9 | 121.7 | 119.4 | 121.7 | 123.3 | 112.9 | 112.2 | 117.2 | 115.5 | 120.8 | 126.4 | 119.2 | 120.8 | 121.3 | 122.9 |
| Std Dev | 13.6 | 9.9 | 13.2 | 7.1 | 8.8 | 10.5 | 10.0 | 10.4 | 14.4 | 12.2 | 8.3 | 10.3 | 9.5 | 10.1 | 10.2 | 13.2 | 14.2 |
| Max | 152 | 138 | 154 | 136 | 134 | 144 | 134 | 132 | 142 | 139 | 128 | 132 | 138 | 132 | 134 | 152 | 147 |
| Min | 94 | 108 | 106 | 110 | 102 | 104 | 100 | 97 | 92 | 98 | 102 | 96 | 106 | 96 | 100 | 105 | 100 |

Units: mmHg

Table 6a-4
Vital Signs: Systolic BP

Blank = Not Obtained

| Subj \ Day | 180 |
|------------|-------|
| 01 | 114 |
| 02 | |
| 03 | 112 |
| 04 | |
| 05 | |
| 06 | 144 |
| 07 | 125 |
| 08 | |
| 09 | 116 |
| 10 | |
| 11 | |
| 12 | 126 |
| 13 | 117 |
| 14 | |
| 15 | 140 |
| 16 | 123 |
| 17 | |
| 18 | |
| 19 | |
| 20 | |
| 21 | |
| Summary: | |
| Average | 124.1 |
| Std Dev | 11.3 |
| Max | 144 |
| Min | 112 |

Dec. 17, 1998

Figure 1: SD & Range Charts for Systolic BP, mmHg

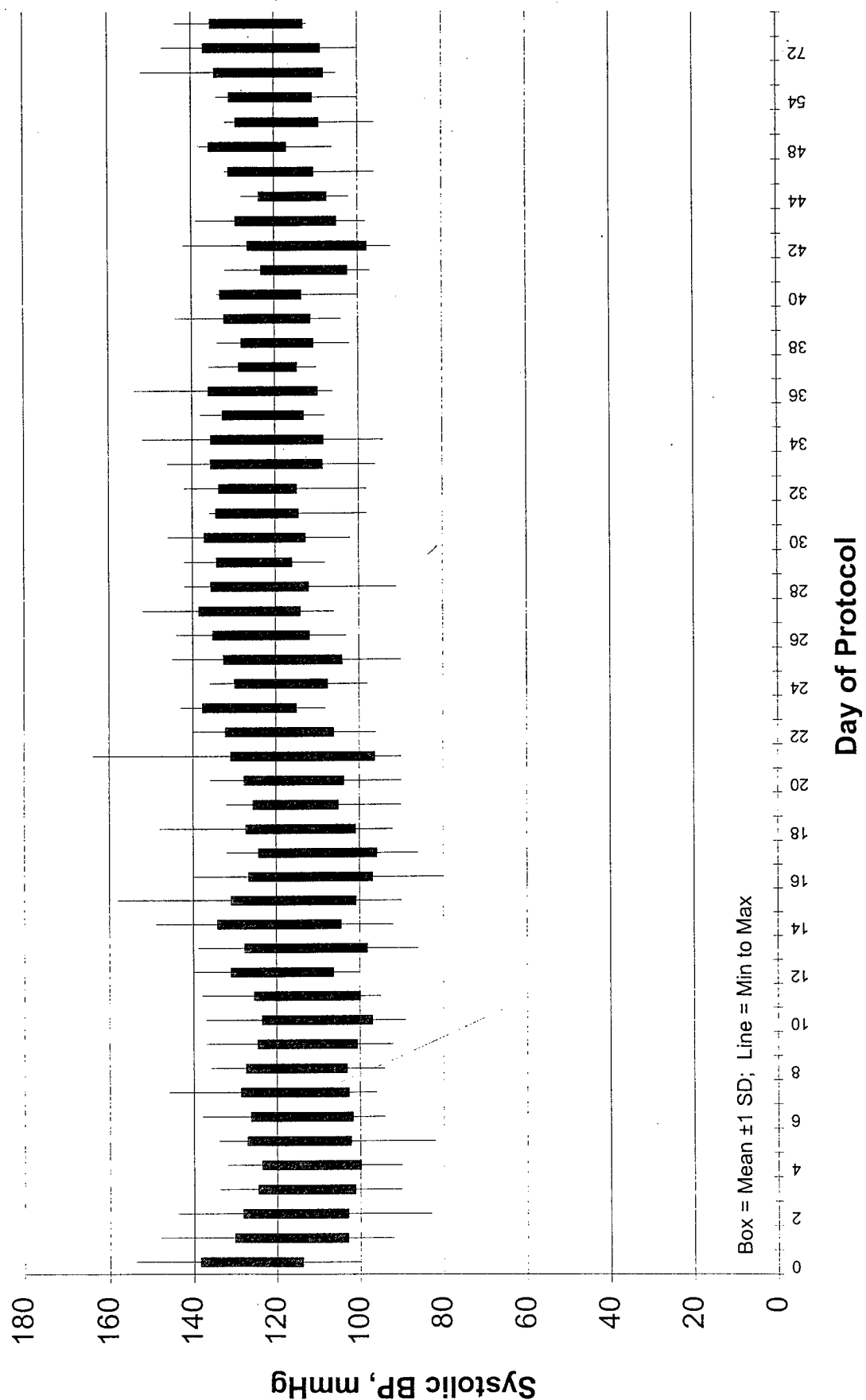
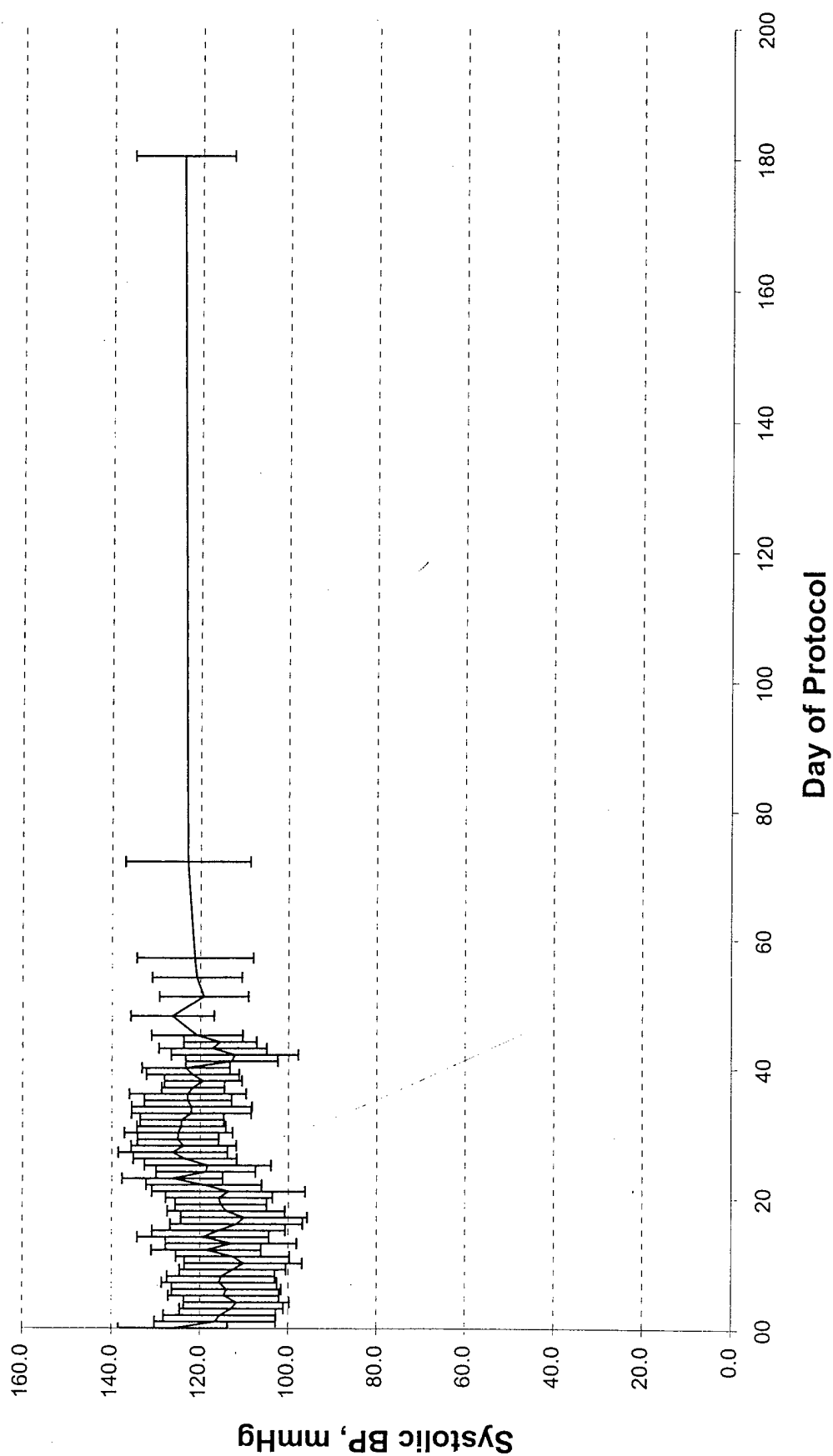


Figure 2: Systolic BP, mmHg



Units: mmHg

Table 6b-1
Vital Signs: Diastolic BP

Blank = Not Obtained

| Subj \ Day | 00 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
|------------|--------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 01 | 64 | 74 | 74 | 60 | 68 | 64 | 68 | 60 | 68 | 65 | 61 | 62 | 64 | 74 | 70 | 71 | 74 | 70 | 68 | 70 | 63 |
| 02 | 72 | 68 | 99 | 68 | 70 | 58 | 56 | 44 | 68 | 63 | 64 | 60 | 74 | 62 | 86 | 84 | 67 | 60 | 50 | 60 | 61 |
| 03 | 56 | 66 | 54 | 69 | 50 | 46 | 52 | 50 | 52 | 58 | 52 | 42 | 50 | 52 | 46 | 56 | 48 | 46 | 48 | 46 | 56 |
| 04 | 80 | 72 | 60 | 66 | 58 | 66 | 58 | 60 | 72 | 66 | 68 | 76 | 86 | 82 | 70 | 68 | 64 | 76 | 67 | 76 | 72 |
| 05 | 68 | 64 | 54 | 58 | 60 | 66 | 56 | 54 | 62 | 58 | 70 | 56 | 60 | 64 | 52 | 58 | 62 | 66 | 60 | 66 | 62 |
| 06 | 90 | 96 | 74 | 58 | 78 | 71 | 80 | 70 | 68 | 61 | 62 | 84 | 68 | 78 | 70 | 72 | 70 | 70 | 66 | 70 | 68 |
| 07 | 84 | 60 | 78 | 60 | 64 | 76 | 72 | 68 | 62 | 77 | 58 | 68 | 76 | 78 | 60 | 74 | 64 | 72 | 64 | 72 | 66 |
| 08 | 70 | 80 | 70 | 64 | 52 | 62 | 59 | 62 | 64 | 53 | 57 | | | | | | | | | | |
| 09 | 66 | 68 | 66 | 64 | 72 | 67 | 62 | 66 | 60 | 72 | 55 | 60 | 56 | 50 | 56 | 74 | 52 | 62 | 60 | 62 | 64 |
| 10 | 68 | 72 | 70 | 62 | 66 | 66 | 70 | 68 | 56 | 73 | 72 | 58 | 69 | 69 | 58 | 72 | 68 | 75 | 70 | 75 | 64 |
| 11 | 88 | 74 | 59 | 60 | 56 | 56 | 60 | 58 | 72 | 78 | 56 | 60 | 60 | 54 | 76 | 58 | 64 | 62 | 64 | 62 | 74 |
| 12 | 78 | 78 | 82 | 76 | 72 | 72 | 67 | 85 | 72 | 66 | 66 | 76 | 84 | 78 | 82 | 68 | 80 | 71 | 82 | 71 | 72 |
| 13 | 64 | 62 | 56 | 57 | 56 | 62 | 46 | 60 | 54 | 56 | 44 | 50 | 48 | 52 | 58 | 52 | 48 | 62 | 60 | 62 | 58 |
| 14 | 84 | 68 | 66 | 67 | 62 | 64 | 74 | 72 | 70 | 80 | 56 | 64 | 74 | 68 | 54 | 58 | 52 | 72 | 64 | 72 | 75 |
| 15 | 71 | 68 | 47 | 58 | 64 | 74 | 60 | 63 | 56 | 52 | 50 | 64 | 56 | 54 | 52 | 68 | 46 | 61 | 59 | 61 | 62 |
| 16 | 60 | 62 | 64 | 60 | 58 | 68 | 60 | 56 | 66 | 68 | 52 | 59 | 64 | 52 | 66 | 60 | 62 | 67 | 60 | 67 | 74 |
| 17 | 76 | 65 | | | | | | | | | | | | | | | | | | | |
| 18 | 73 | 61 | 66 | 68 | 64 | 60 | 58 | 64 | 48 | 60 | 54 | 64 | 58 | 50 | 60 | 56 | 60 | 52 | 65 | 52 | 65 |
| 19 | 80 | 60 | 70 | 77 | 90 | 71 | 56 | 58 | 80 | 76 | 66 | 74 | 72 | 66 | 60 | 64 | 52 | 47 | 66 | 47 | 66 |
| 20 | 70 | 70 | 71 | 80 | 68 | 88 | 88 | 60 | 66 | 72 | 71 | 64 | 60 | 76 | 64 | 58 | 62 | 66 | 64 | 66 | 72 |
| 21 | 60 | 54 | 44 | 52 | 56 | 54 | 49 | 57 | 57 | 60 | 58 | 56 | 54 | 55 | 64 | 54 | 48 | 51 | 64 | 58 | 52 |
| Summary: | Diastolic BP, mmHg | | | | | | | | | | | | | | | | | | | | |
| average | 72.5 | 68.7 | 66.2 | 64.2 | 64.2 | 65.6 | 62.6 | 61.8 | 63.7 | 65.7 | 59.6 | 63.0 | 64.9 | 63.9 | 63.4 | 64.5 | 60.2 | 63.6 | 63.2 | 63.9 | 65.6 |
| stdev | 9.5 | 8.9 | 12.6 | 7.3 | 9.4 | 8.9 | 10.4 | 8.7 | 8.1 | 8.5 | 7.7 | 9.7 | 10.8 | 11.3 | 10.4 | 8.7 | 9.7 | 9.1 | 7.2 | 8.7 | 6.5 |
| max | 90 | 96 | 99 | 80 | 90 | 88 | 88 | 85 | 80 | 80 | 72 | 84 | 86 | 82 | 86 | 84 | 80 | 76 | 82 | 76 | 75 |
| min | 56 | 54 | 44 | 52 | 50 | 46 | 46 | 44 | 48 | 52 | 44 | 42 | 48 | 50 | 46 | 52 | 46 | 46 | 48 | 46 | 52 |

Units: mmHg

Table 6b-2
Vital Signs: Diastolic BP

Blank = Not Obtained

| Subj \ Day | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 |
|------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 01 | 70 | 62 | 72 | 86 | 68 | 64 | 60 | 66 | 70 | 64 | 66 | 72 | 70 | 56 | 54 | 64 | 54 | 64 | 62 | 74 | 62 |
| 02 | 74 | 74 | 57 | 72 | 74 | 64 | 74 | 78 | 61 | 68 | 67 | 73 | | 70 | 63 | | | | | | |
| 03 | 56 | 58 | 54 | 50 | 54 | 50 | 60 | 47 | 52 | 78 | 52 | 58 | 56 | 46 | 68 | 56 | 44 | 56 | 64 | 52 | 54 |
| 04 | 69 | 86 | 70 | 84 | 84 | 82 | 76 | 84 | 54 | 76 | 76 | 74 | 82 | 82 | 70 | 66 | 68 | | | | |
| 05 | 64 | 70 | 76 | 84 | 74 | | 72 | 86 | | | | | | | | | | | | 84 | |
| 06 | 70 | 64 | 76 | 82 | 72 | 70 | 72 | 78 | 88 | 73 | 88 | 66 | 79 | 78 | 88 | 80 | 78 | 72 | 76 | 57 | 84 |
| 07 | 72 | 70 | 66 | 84 | 65 | 62 | 68 | 70 | 54 | 68 | 60 | 66 | | | 64 | 70 | 64 | 50 | 78 | | |
| 08 | | | | | | | | | | | | | | | | | | | | 71 | 58 |
| 09 | 58 | 60 | 70 | 69 | 68 | 80 | 76 | 97 | 86 | 63 | 56 | 64 | 56 | 54 | | 66 | 58 | 64 | 56 | 80 | 54 |
| 10 | 64 | 71 | 86 | 80 | 74 | 85 | 78 | 70 | 72 | 68 | 55 | 68 | 64 | 74 | 64 | 68 | 72 | 76 | 66 | 78 | 48 |
| 11 | 64 | 72 | 64 | 76 | 70 | 74 | 79 | 80 | 80 | 80 | 86 | 82 | 70 | 68 | 72 | 78 | 71 | 78 | 70 | 80 | 74 |
| 12 | 72 | 82 | 66 | 78 | 70 | 74 | 74 | 80 | 80 | 66 | 66 | 79 | 75 | 77 | 80 | 60 | 73 | 66 | 78 | 69 | 58 |
| 13 | 60 | 58 | 65 | 66 | 66 | 60 | 66 | 64 | 67 | 62 | 57 | 63 | 76 | 58 | 61 | 53 | 66 | 64 | 62 | 71 | |
| 14 | 68 | 85 | 89 | 66 | 68 | 80 | 85 | 72 | 65 | 80 | 84 | 72 | 83 | 76 | 65 | 80 | 66 | 67 | 68 | 67 | 54 |
| 15 | 59 | 61 | 81 | 68 | 72 | 66 | 73 | 70 | 64 | 62 | 56 | 74 | 98 | 70 | 72 | 60 | 60 | 71 | 66 | 64 | 54 |
| 16 | 70 | 72 | | 66 | 58 | 71 | 92 | 86 | 57 | | 70 | 84 | 71 | 72 | 65 | 68 | 75 | 65 | 74 | | 68 |
| 17 | | | | 66 | | | | | | | | | | | | | | | | | |
| 18 | 61 | 62 | | | 54 | 62 | 80 | | 90 | 82 | | 68 | 80 | 72 | 82 | | 58 | 78 | | 67 | 80 |
| 19 | 56 | 70 | 62 | 74 | 72 | 64 | 60 | 70 | 77 | 89 | 72 | 76 | 72 | 72 | 68 | 78 | 84 | 78 | 90 | 87 | 74 |
| 20 | 76 | 48 | 80 | | 62 | 64 | 76 | 78 | 72 | 74 | 68 | 70 | 71 | 74 | 70 | | | | 78 | 70 | 72 |
| 21 | 63 | 68 | | | 64 | 61 | | 71 | 66 | | | 63 | 59 | 77 | 56 | 64 | | | 57 | 68 | 64 |
| Summary: | | | | | | | | | | | | | | | | | | | | | |
| average | 65.6 | 68.1 | 70.9 | 73.6 | 67.8 | 68.5 | 73.4 | 74.8 | 69.7 | 72.1 | 67.4 | 70.7 | 72.6 | 69.2 | 68.4 | 67.4 | 66.1 | 67.8 | 69.7 | 71.2 | 63.9 |
| stdev | 6.2 | 9.7 | 9.9 | 9.5 | 7.4 | 9.2 | 8.5 | 10.8 | 11.9 | 8.2 | 11.4 | 6.9 | 10.9 | 9.8 | 8.8 | 8.6 | 10.2 | 8.4 | 9.3 | 9.3 | 10.9 |
| max | 76 | 86 | 89 | 86 | 84 | 85 | 92 | 97 | 90 | 89 | 88 | 84 | 98 | 82 | 88 | 80 | 84 | 78 | 90 | 87 | 84 |
| min | 56 | 48 | 54 | 50 | 54 | 50 | 60 | 47 | 52 | 62 | 52 | 58 | 56 | 46 | 54 | 53 | 44 | 50 | 56 | 52 | 48 |

Units: mmHg

Table 6b-3
Vital Signs: Diastolic BP

Blank = Not Obtained

| Subj \ Day | 42 | 43 | 44 | 45 | 48 | 51 | 54 | 57 | 72 | 180 |
|------------|------|------|------|------|------|------|------|------|------|------|
| 01 | 78 | 56 | 64 | 70 | 64 | 72 | 62 | 54 | 66 | 64 |
| 02 | | | | 58 | | | | | | |
| 03 | 50 | 68 | 58 | | 56 | 60 | 56 | 54 | 60 | 60 |
| 04 | | | | | | | | | | |
| 05 | | | | 88 | | | | | | |
| 06 | 70 | 78 | 62 | | 86 | 78 | 80 | 70 | 62 | 84 |
| 07 | 72 | 74 | | | | 64 | 56 | 80 | 64 | 82 |
| 08 | | | | | | | | | | 66 |
| 09 | 60 | 58 | 68 | 62 | 62 | 62 | 62 | 68 | 74 | 76 |
| 10 | 66 | 76 | 74 | 74 | | 60 | 72 | | | |
| 11 | 48 | 65 | 68 | 80 | | | | | | |
| 12 | 85 | 86 | 64 | 73 | 78 | 77 | 72 | 72 | 78 | 74 |
| 13 | 52 | 60 | 60 | 63 | 60 | 70 | 60 | 56 | 73 | 64 |
| 14 | | | | | | | | | | |
| 15 | 55 | 68 | 50 | 66 | 60 | 60 | 66 | 60 | 81 | 78 |
| 16 | 66 | 66 | 64 | | | | | | | 80 |
| 17 | | | | | | | | | | |
| 18 | 78 | 79 | | 62 | 86 | 52 | 80 | 68 | 82 | |
| 19 | 74 | 46 | 72 | 80 | 88 | 74 | 78 | 65 | 68 | |
| 20 | 36 | 64 | 74 | 76 | 68 | 66 | 72 | 58 | | |
| 21 | 62 | 60 | 64 | 66 | 64 | 68 | 63 | 61 | 84 | |
| Summary: | | | | | | | | | | |
| average | 63.5 | 66.9 | 64.8 | 70.6 | 70.2 | 66.4 | 67.6 | 63.8 | 72.0 | 72.8 |
| stdev | 13.4 | 10.4 | 6.7 | 8.8 | 12.0 | 7.7 | 8.6 | 8.1 | 8.5 | 8.6 |
| max | 85 | 86 | 74 | 88 | 88 | 78 | 80 | 80 | 84 | 84 |
| min | 36 | 46 | 50 | 58 | 56 | 52 | 56 | 54 | 60 | 60 |

Figure 3: SD & Range Charts for Diastolic BP, mmHg

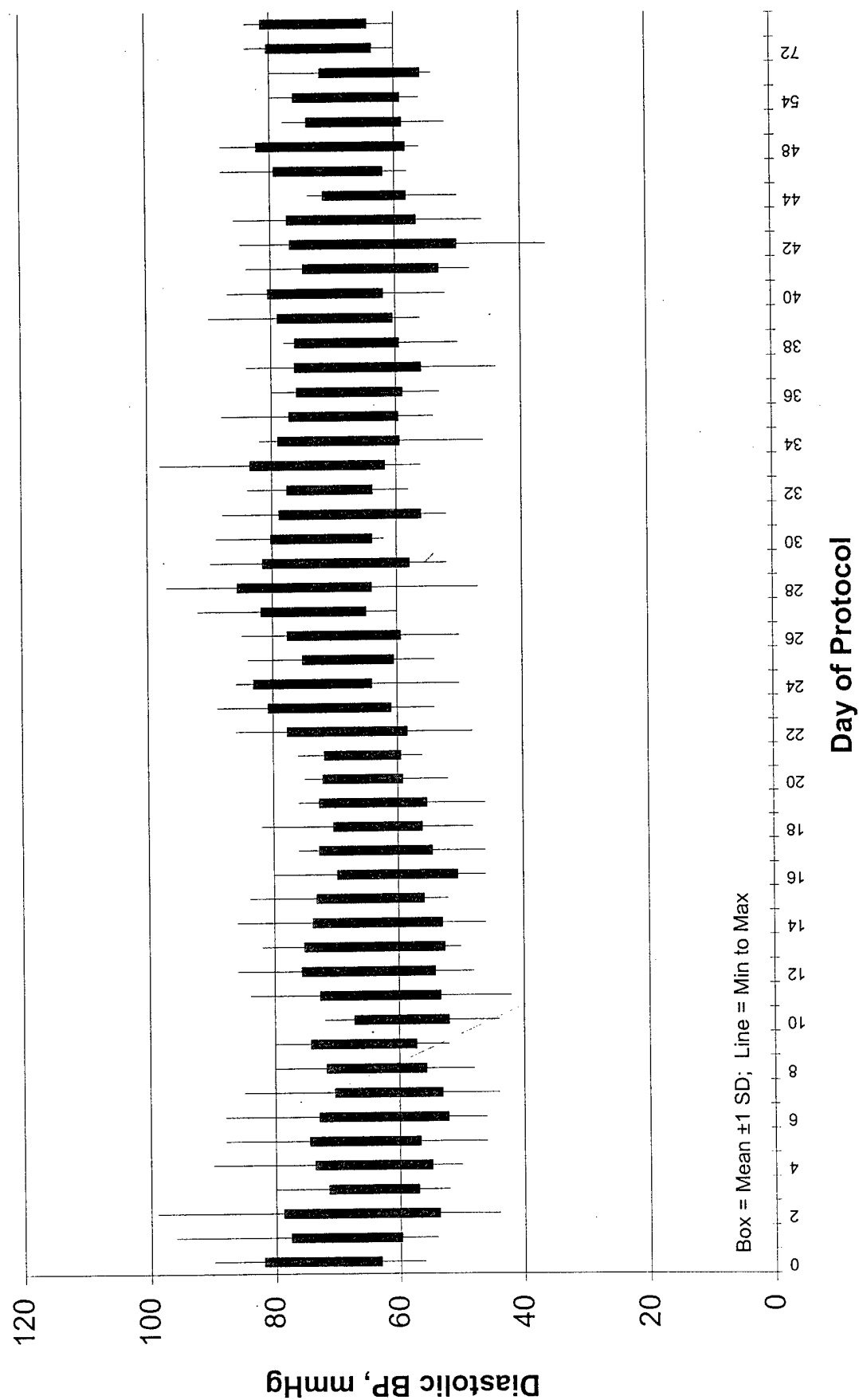
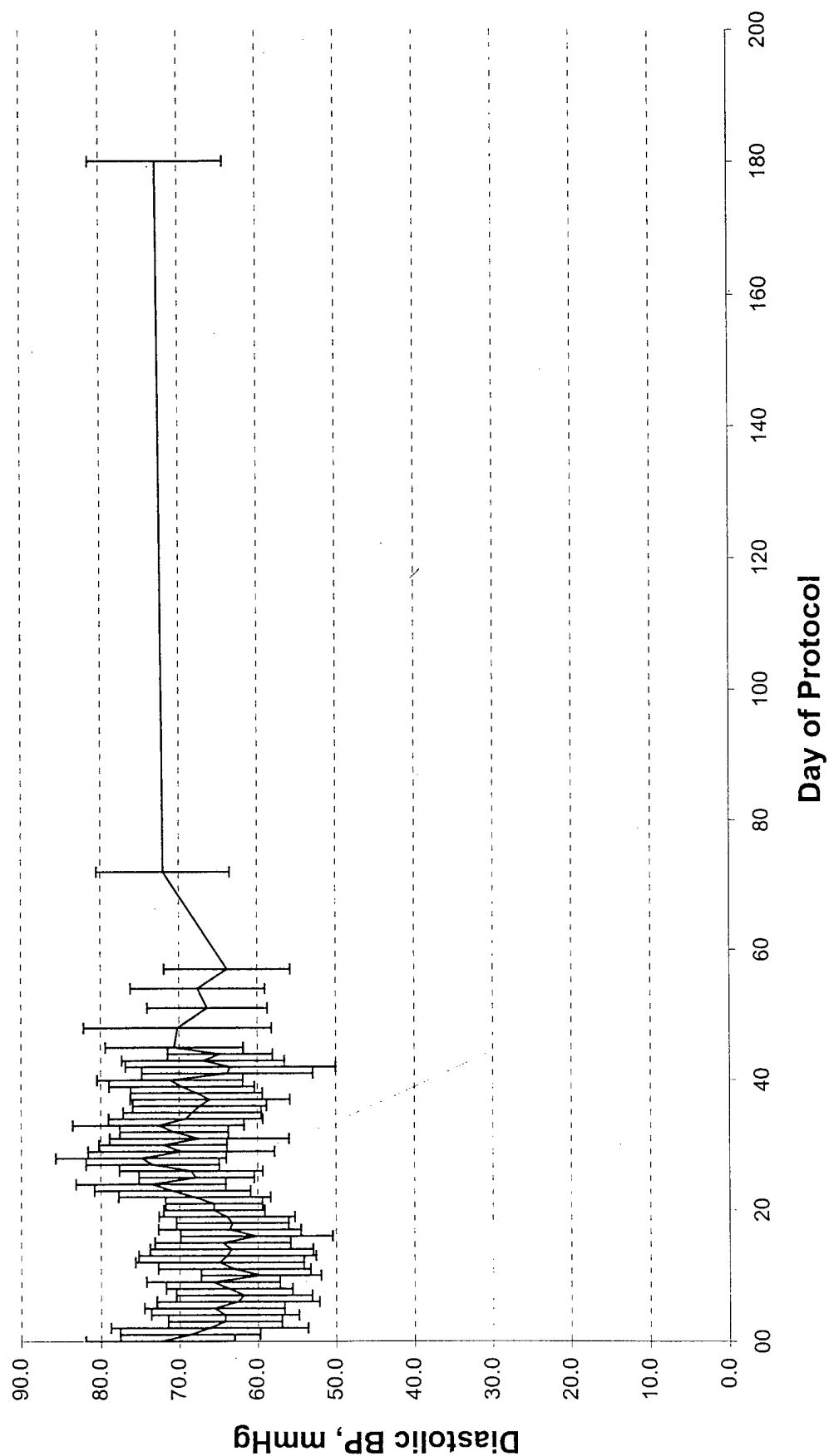


Figure 4: Diastolic BP, mmHg



Units: BPM

Table 6c-1
Vital Signs: Heart Rate

Blank = Not Obtained

| Subj \ Day | 00 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
|------------|-----------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 01 | 89 | 71 | 70 | 61 | 62 | 52 | 63 | 71 | 74 | 60 | 57 | 56 | 71 | 57 | 86 | 58 | 62 | 82 | 76 | 66 | 66 |
| 02 | 87 | 53 | 98 | 56 | 59 | 58 | 65 | 54 | 63 | 53 | 71 | 58 | 56 | 50 | 66 | 76 | 61 | 56 | 50 | 55 | 61 |
| 03 | 77 | 64 | 73 | 69 | 51 | 57 | 52 | 61 | 61 | 55 | 56 | 68 | 65 | 87 | 69 | 67 | 67 | 59 | 58 | 57 | 91 |
| 04 | 80 | 65 | 65 | 64 | 76 | 64 | 64 | 69 | 69 | 67 | 69 | 66 | 84 | 84 | 76 | 76 | 73 | 83 | 98 | 89 | 83 |
| 05 | 54 | 54 | 50 | 65 | 48 | 59 | 57 | 67 | 54 | 53 | 53 | 62 | 53 | 54 | 48 | 57 | 53 | 50 | 56 | 57 | 60 |
| 06 | 87 | 69 | 57 | 53 | 64 | 70 | 61 | 59 | 59 | 58 | 61 | 66 | 60 | 67 | 61 | 69 | 57 | 65 | 67 | 66 | 69 |
| 07 | 62 | 47 | 42 | 47 | 54 | 47 | 67 | 63 | 54 | 66 | 66 | 67 | 61 | 70 | 73 | 79 | 77 | 64 | 69 | 67 | 79 |
| 08 | 46 | 61 | 62 | 56 | 53 | 55 | 51 | 51 | 54 | 55 | 57 | | | | | | | | | | |
| 09 | 52 | 52 | 50 | 53 | 51 | 53 | 47 | 52 | 52 | 52 | 55 | 50 | 46 | 50 | 48 | 57 | 48 | 57 | 47 | 49 | 47 |
| 10 | 83 | 74 | 71 | 74 | 83 | 74 | 76 | 69 | 83 | 74 | 70 | 74 | 64 | 63 | 93 | 66 | 66 | 59 | 91 | 89 | 66 |
| 11 | 107 | 93 | 75 | 64 | 66 | 65 | 64 | 67 | 63 | 73 | 61 | 65 | 61 | 58 | 61 | 60 | 63 | 67 | 65 | 71 | 86 |
| 12 | 60 | 89 | 67 | 60 | 61 | 66 | 65 | 64 | 65 | 79 | 66 | 60 | 63 | 67 | 60 | 81 | 67 | 71 | 69 | 69 | 70 |
| 13 | 64 | 43 | 42 | 46 | 43 | 46 | 49 | 46 | 48 | 48 | 44 | 45 | 44 | 42 | 43 | 46 | 50 | 43 | 45 | 44 | 41 |
| 14 | 60 | 45 | 58 | 48 | 46 | 48 | 48 | 46 | 45 | 50 | 46 | 48 | 48 | 50 | 45 | 46 | 54 | 48 | 50 | 46 | 48 |
| 15 | 70 | 65 | 77 | 64 | 58 | 69 | 59 | 59 | 59 | 58 | 62 | 59 | 64 | 60 | 57 | 48 | 53 | 54 | 71 | 60 | 60 |
| 16 | 82 | 85 | 70 | 71 | 74 | 69 | 65 | 70 | 71 | 73 | 70 | 69 | 63 | 79 | 70 | 67 | 79 | 67 | 69 | 70 | 67 |
| 17 | 67 | 76 | | | | | | | | | | | | | | | | | | | |
| 18 | 70 | 64 | 60 | 73 | 64 | 63 | 61 | 79 | 62 | 64 | 58 | 78 | 60 | 66 | 60 | 60 | 66 | 62 | 66 | 66 | 67 |
| 19 | 70 | 56 | 67 | 65 | 70 | 76 | 67 | 74 | 67 | 81 | 60 | 77 | 69 | 73 | 66 | 87 | 64 | 63 | 69 | 70 | 59 |
| 20 | 62 | 54 | 65 | 64 | 52 | 63 | 63 | 63 | 55 | 92 | 90 | 59 | 60 | 67 | 66 | 60 | 61 | 59 | 60 | 62 | 69 |
| 21 | 71 | 70 | 59 | 70 | 56 | 69 | 63 | 61 | 70 | 66 | 57 | 63 | 60 | 57 | 78 | 59 | 59 | 66 | 67 | 58 | 74 |
| Summary | Heart Rate, BPM | | | | | | | | | | | | | | | | | | | | |
| Average | 71.5 | 64.0 | 64.2 | 60.7 | 59.7 | 60.7 | 60.2 | 62.3 | 60.9 | 63.7 | 61.7 | 62.6 | 60.7 | 63.6 | 63.8 | 64.4 | 62.3 | 61.6 | 65.3 | 64.1 | 66.1 |
| Std Dev | 14.6 | 13.9 | 12.9 | 8.6 | 10.5 | 9.0 | 7.5 | 9.0 | 9.3 | 11.8 | 10.0 | 9.0 | 9.2 | 12.0 | 13.4 | 11.8 | 8.6 | 10.2 | 13.6 | 12.0 | 13.0 |
| Max | 107 | 93 | 98 | 74 | 83 | 76 | 76 | 79 | 83 | 92 | 90 | 78 | 84 | 87 | 93 | 87 | 79 | 83 | 98 | 89 | 91 |
| Min | 46 | 43 | 42 | 46 | 43 | 46 | 47 | 46 | 45 | 48 | 44 | 45 | 44 | 42 | 43 | 46 | 48 | 43 | 45 | 44 | 41 |

Units: BPM

Table 6c-2
Vital Signs: Heart Rate

Blank = Not Obtained

| Subj \ Day | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 |
|------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 01 | 71 | 71 | 77 | 96 | 80 | 91 | 61 | 71 | 67 | 60 | 66 | 70 | 62 | 65 | 65 | 62 | 73 | 73 | 69 | 93 | 62 |
| 02 | 65 | 81 | 52 | 66 | 71 | 69 | 85 | 77 | 79 | 87 | 88 | 114 | | 107 | 85 | | | | | | |
| 03 | 60 | 57 | 70 | 48 | 57 | 60 | 59 | 71 | 63 | 58 | 58 | 69 | 64 | 63 | 67 | 62 | 62 | 61 | 73 | 85 | 64 |
| 04 | 83 | 92 | 110 | 89 | 93 | 93 | 91 | 100 | 71 | 83 | 74 | 85 | 81 | 83 | | | 78 | | | | |
| 05 | 57 | 53 | 66 | 73 | 53 | | 76 | 63 | | | | | | | | | | | | | |
| 06 | 64 | 69 | 83 | 87 | 87 | 89 | 69 | 88 | 89 | 73 | 77 | 70 | 76 | 83 | 73 | 70 | 76 | 85 | 74 | 69 | 96 |
| 07 | 89 | 70 | 91 | 89 | 70 | 93 | 85 | 74 | 60 | 77 | 61 | 69 | | | 66 | 53 | 66 | 49 | 76 | 50 | |
| 08 | | | | | | | | | | | | | | | | | | | | | |
| 09 | 46 | 50 | 63 | 60 | 74 | 96 | 60 | 83 | 63 | 61 | 65 | 79 | 57 | 63 | | 56 | 62 | 54 | 50 | 60 | 59 |
| 10 | 70 | 85 | 81 | 83 | 70 | 104 | 107 | 76 | 89 | 91 | 91 | 73 | 81 | 91 | 93 | 63 | 81 | 79 | 54 | 87 | 60 |
| 11 | 63 | 109 | 71 | 83 | 73 | 87 | 79 | 67 | 77 | 74 | 71 | 74 | 67 | 79 | 76 | 74 | 74 | 74 | 76 | 83 | 74 |
| 12 | 66 | 70 | 71 | 83 | 83 | 89 | 77 | 85 | 74 | 70 | 64 | 81 | 66 | 81 | 71 | 65 | 69 | 70 | 89 | 76 | 93 |
| 13 | 45 | 48 | 69 | 74 | 62 | 65 | 44 | 50 | 53 | 74 | 48 | 63 | 81 | 59 | 56 | 56 | 62 | 55 | 54 | 63 | 50 |
| 14 | 50 | 57 | 83 | 57 | 60 | 64 | 59 | 56 | 62 | 56 | 53 | 53 | 55 | 70 | 52 | 79 | 50 | 55 | 53 | 53 | |
| 15 | 52 | 61 | 81 | 85 | 74 | 71 | 79 | 64 | 74 | 79 | 76 | 81 | 94 | 73 | 92 | 79 | 69 | 83 | 83 | 85 | 83 |
| 16 | 74 | 85 | | 104 | 85 | 101 | 81 | 81 | 87 | | 79 | 70 | 77 | 70 | 73 | 81 | 83 | 77 | 71 | 89 | 91 |
| 17 | | | | | | | | | | | | | | | | | | | | | |
| 18 | 73 | 77 | | | 85 | 89 | 89 | | 96 | 87 | | 81 | 91 | 83 | 104 | | 85 | 89 | | 79 | 87 |
| 19 | 56 | 79 | 67 | 70 | 70 | 66 | 74 | 64 | 79 | 89 | 66 | 70 | 70 | 79 | 69 | 73 | 73 | 69 | 81 | 64 | 64 |
| 20 | 70 | 63 | 66 | | 58 | 62 | 63 | 60 | 63 | 61 | | | | 61 | 53 | | | | 61 | 51 | 54 |
| 21 | 60 | 62 | | | 61 | 58 | | 55 | 58 | | | 62 | 69 | 77 | 61 | 62 | | | 57 | 65 | 61 |
| Summary | | | | | | | | | | | | | | | | | | | | | |
| Average | 64.1 | 70.9 | 75.1 | 77.9 | 72.5 | 81.7 | 74.3 | 72.4 | 73.3 | 73.8 | 69.1 | 75.1 | 73.0 | 75.6 | 73.0 | 67.2 | 70.9 | 69.5 | 68.9 | 72.5 | 72.1 |
| Std Dev | 11.7 | 15.7 | 13.4 | 15.0 | 11.4 | 15.5 | 15.0 | 13.0 | 12.3 | 11.8 | 12.0 | 13.0 | 11.6 | 12.3 | 14.9 | 9.2 | 9.4 | 12.8 | 12.4 | 14.4 | 15.7 |
| Max | 89 | 109 | 110 | 104 | 93 | 104 | 107 | 100 | 96 | 91 | 91 | 114 | 94 | 107 | 104 | 81 | 85 | 89 | 89 | 93 | 96 |
| Min | 45 | 48 | 52 | 48 | 53 | 60 | 44 | 50 | 53 | 56 | 48 | 53 | 55 | 59 | 52 | 53 | 50 | 49 | 50 | 50 | 50 |

Units: BPM

Table 6c-3
Vital Signs: Heart Rate

Blank = Not Obtained

| Subj \ Day | 42 | 43 | 44 | 45 | 48 | 51 | 54 | 57 | 72 | 180 |
|------------|------|------|------|------|------|------|------|------|------|------|
| 01 | 63 | 64 | 59 | 61 | 64 | 53 | 69 | 69 | 77 | 76 |
| 02 | | | | | | | | | | |
| 03 | 87 | 79 | 74 | 74 | 81 | 81 | 66 | 66 | 73 | 62 |
| 04 | | | | | | | | | | |
| 05 | | | | | | | | | | |
| 06 | 59 | 52 | 59 | 71 | 77 | 67 | 77 | 59 | 61 | 77 |
| 07 | 69 | 46 | | | | 71 | 70 | 89 | 73 | 50 |
| 08 | | | | | | | | | | |
| 09 | 50 | 45 | 69 | 52 | 51 | 60 | 57 | 68 | 53 | 69 |
| 10 | 66 | 65 | 79 | 87 | | 79 | 93 | | | |
| 11 | 64 | 62 | 73 | 89 | | | | | | |
| 12 | 74 | 74 | 60 | 62 | 76 | 85 | 66 | 85 | 69 | 70 |
| 13 | 45 | 50 | 60 | 69 | 53 | 61 | 61 | 52 | 61 | 65 |
| 14 | | | | | | | | | | |
| 15 | 60 | 71 | 65 | 76 | 76 | 70 | 73 | 58 | 107 | 93 |
| 16 | 63 | 73 | 91 | | | | | | | |
| 17 | | | | | | | | | | |
| 18 | 59 | 59 | 83 | 83 | 76 | 83 | 91 | 85 | 89 | |
| 19 | 76 | 76 | 69 | | 85 | 81 | 79 | 76 | 59 | |
| 20 | 57 | 62 | 61 | 61 | 58 | 73 | 56 | 59 | | |
| 21 | 61 | 74 | 77 | 69 | 77 | 91 | 74 | 70 | 62 | |
| Summary | | | | | | | | | | |
| Average | 63.7 | 62.7 | 69.4 | 71.4 | 69.7 | 72.0 | 71.5 | 69.6 | 72.2 | 70.3 |
| Std Dev | 10.3 | 11.2 | 10.1 | 11.3 | 11.7 | 11.1 | 11.4 | 12.0 | 15.5 | 12.6 |
| Max | 87 | 79 | 91 | 89 | 85 | 85 | 93 | 89 | 107 | 93 |
| Min | 45 | 45 | 59 | 52 | 51 | 53 | 56 | 52 | 53 | 50 |

Figure 5: SD & Range Charts for Heart Rate, BPM

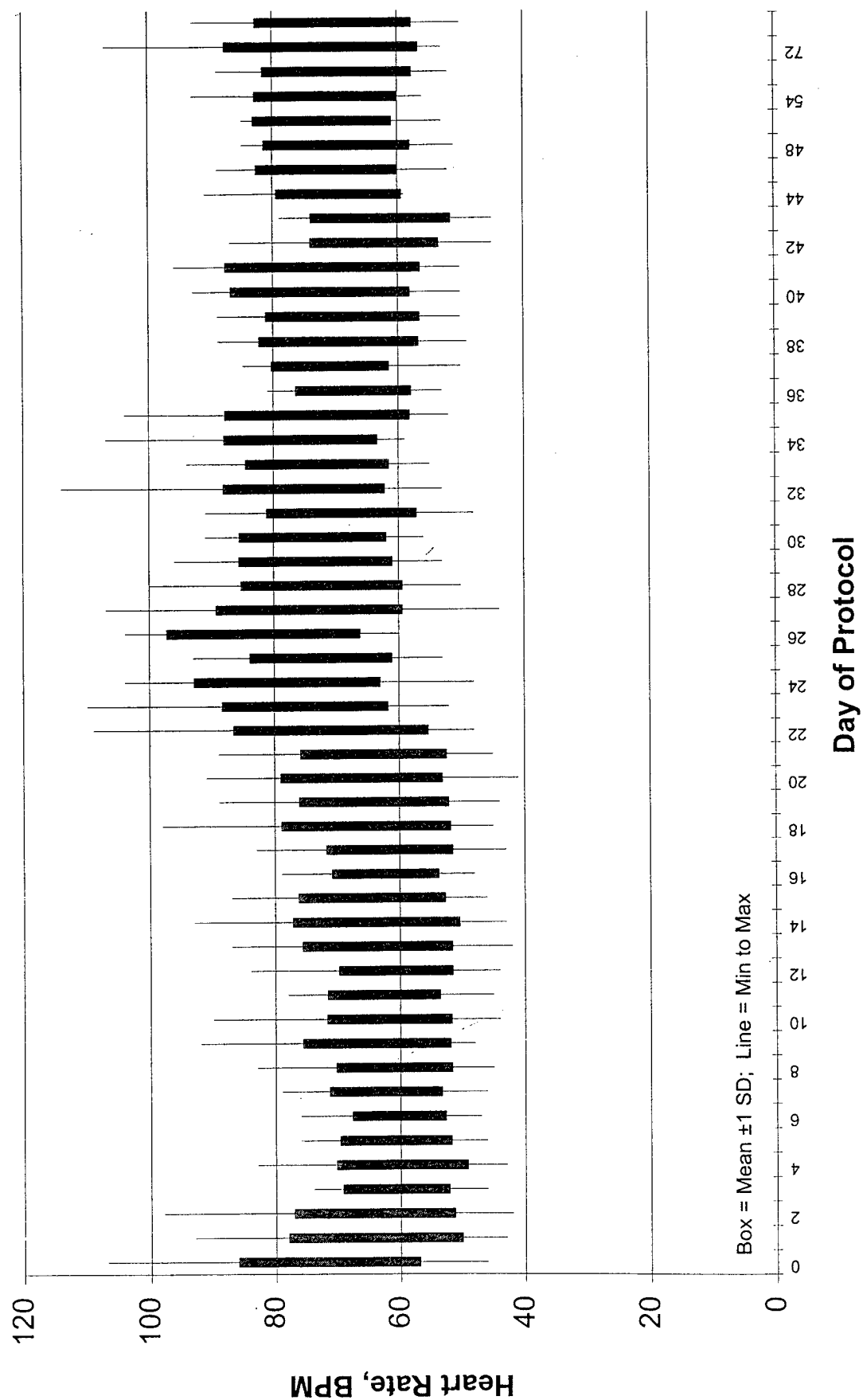
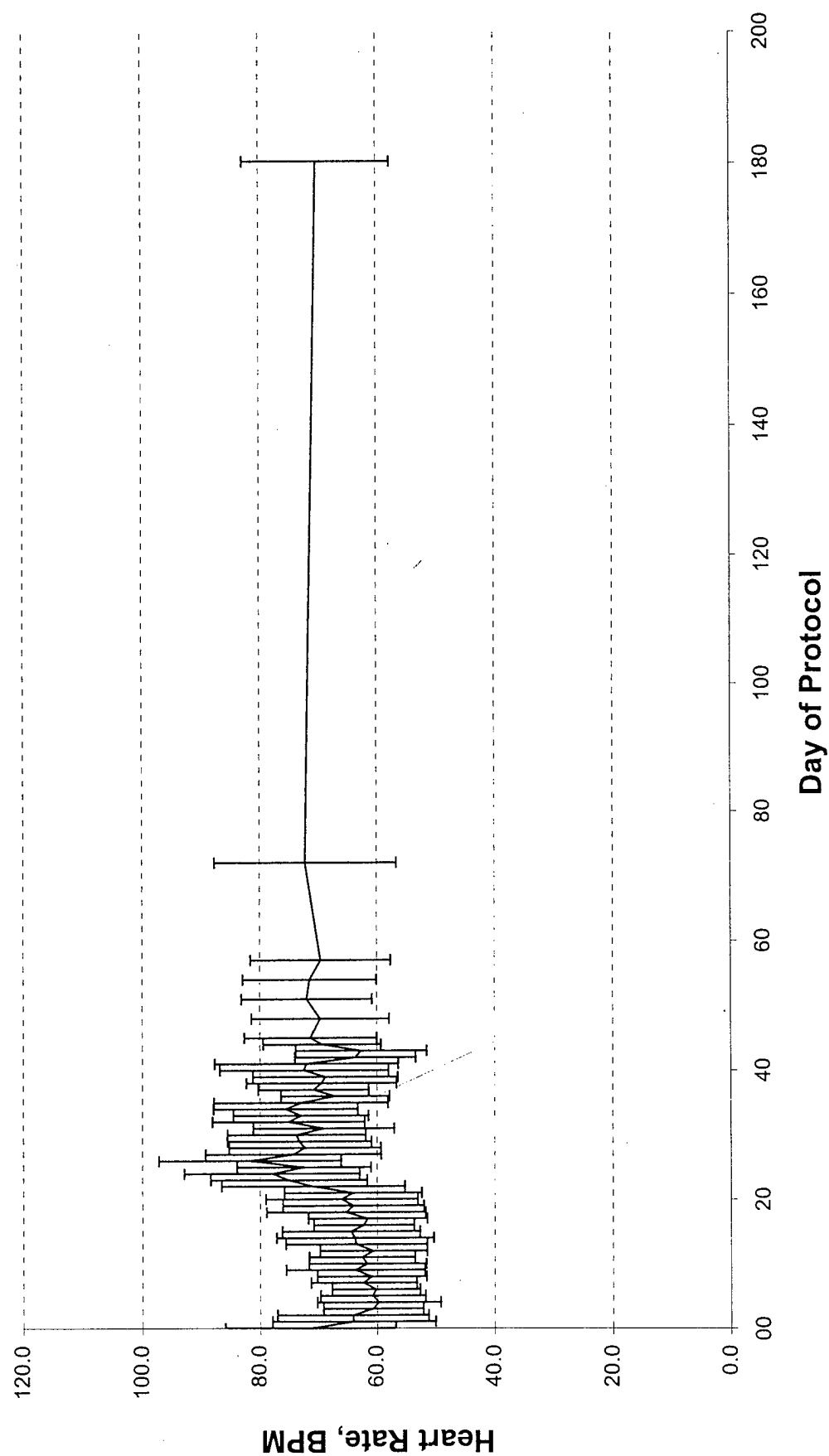


Figure 6: Heart Rate, BPM



Units: °C

Table 6d-1
Vital Signs: Body Temperature

Blank = Not Obtained

| Subj \ Day | 00 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
|------------|----------------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 01 | 37.0 | 35.8 | 36.1 | 35.6 | 35.3 | 35.7 | 36.2 | 35.6 | 36.1 | 36.2 | 35.7 | 35.6 | 35.5 | 35.5 | 36.1 | 35.5 | 36.1 | 36.5 | 36.0 | 35.9 | 36.4 |
| 02 | | 36.4 | 36.2 | 35.8 | 38.7 | 35.5 | 36.2 | 36.3 | 36.6 | 36.8 | 37.1 | 36.7 | 36.3 | 36.2 | 35.4 | 36.2 | 35.5 | 35.5 | 35.6 | 36.2 | 35.5 |
| 03 | 36.6 | 36.6 | 36.6 | 36.1 | 36.4 | 36.7 | 36.6 | 36.4 | 37.0 | 36.8 | 37.1 | 36.7 | 36.3 | 36.6 | 36.1 | 36.7 | 36.7 | 37.0 | 37.0 | 36.7 | 36.8 |
| 04 | 36.9 | 36.7 | 36.7 | 36.4 | 36.7 | 36.7 | 36.5 | 36.8 | 36.7 | 36.8 | 36.5 | 36.7 | 36.8 | 36.9 | 36.9 | 36.7 | 36.9 | 36.5 | 37.8 | 37.7 | 36.6 |
| 05 | 36.3 | 36.1 | 36.2 | 36.7 | 35.8 | 35.9 | 36.2 | 36.4 | 36.1 | 36.2 | 36.2 | 36.0 | 36.3 | 36.3 | 36.3 | 36.0 | 36.0 | 35.9 | 36.5 | 35.9 | 36.4 |
| 06 | 37.0 | 36.6 | 36.0 | 35.9 | 34.4 | 36.0 | 36.0 | 36.2 | 35.8 | 36.3 | 35.8 | 36.3 | 35.9 | 35.9 | 35.9 | 36.0 | 36.3 | 36.8 | 36.6 | 36.7 | 36.3 |
| 07 | 36.2 | 36.3 | 35.4 | 35.9 | 36.7 | 35.9 | 36.0 | 36.2 | 35.8 | 36.3 | 35.8 | 36.3 | 35.9 | 35.9 | 35.9 | 36.0 | 36.3 | 36.8 | 36.6 | 36.7 | 36.3 |
| 08 | 36.6 | 36.0 | 36.3 | 36.1 | 35.9 | 36.1 | 36.1 | 36.0 | 36.0 | 36.4 | 36.2 | | | | | | | | | | |
| 09 | 36.6 | 36.1 | 36.6 | 36.0 | 36.1 | 36.0 | 36.0 | 36.2 | 36.2 | 36.2 | 36.4 | 36.1 | 35.8 | 36.2 | 36.1 | 36.2 | 36.3 | 36.3 | 35.9 | 36.1 | 36.1 |
| 10 | 37.0 | 36.7 | 36.9 | 36.7 | 36.9 | 36.9 | 37.4 | 37.1 | 36.3 | 36.4 | 36.9 | 36.8 | 36.8 | 36.7 | 35.5 | 36.7 | 36.9 | 36.9 | 36.9 | 38.1 | 36.5 |
| 11 | 36.8 | 37.6 | 37.3 | 36.6 | 36.6 | 36.0 | 36.7 | 36.4 | 36.6 | 36.7 | 36.7 | 36.3 | 36.4 | 36.2 | 36.3 | 36.3 | 36.0 | 36.2 | 35.8 | 36.4 | 36.2 |
| 12 | 35.6 | 35.6 | 35.5 | 35.6 | 35.6 | 35.8 | 35.0 | 35.6 | 36.0 | 36.3 | 35.9 | 35.7 | 36.0 | 35.6 | 35.5 | 36.4 | 35.6 | 36.2 | 36.4 | 36.1 | 35.5 |
| 13 | 36.9 | 36.2 | 36.0 | 35.9 | 36.1 | 36.0 | 35.9 | 36.0 | 36.2 | 36.2 | 35.5 | 35.9 | 35.7 | 35.7 | 36.1 | 35.6 | 35.0 | 36.2 | 35.5 | 35.8 | 35.8 |
| 14 | 36.5 | 36.6 | 36.4 | 36.3 | 36.4 | 36.4 | 36.3 | 36.3 | 36.2 | 36.4 | 36.5 | 36.5 | 36.5 | 36.1 | 36.5 | 36.6 | 36.4 | 36.6 | 36.5 | 36.5 | 36.5 |
| 15 | 35.6 | 35.6 | 36.2 | 35.8 | 36.0 | 35.6 | 35.4 | 36.0 | 36.2 | 36.1 | 35.7 | 35.5 | 35.7 | 35.7 | 35.7 | 35.3 | 36.0 | 36.0 | 36.0 | 36.0 | 35.5 |
| 16 | 36.5 | 36.7 | 36.2 | 36.0 | 36.4 | 36.3 | 35.9 | 36.4 | 36.3 | 36.4 | 36.2 | 36.0 | 36.5 | 36.5 | 36.2 | 36.0 | 36.0 | 36.5 | 36.1 | 36.3 | 36.2 |
| 17 | 37.0 | 36.1 | | | | | | | | | | | | | | | | | | | |
| 18 | 36.4 | 36.0 | 36.2 | 36.1 | 36.0 | 36.2 | 36.7 | 36.1 | 36.1 | 36.0 | 36.0 | 36.1 | 36.1 | 36.1 | 36.4 | 36.2 | 36.4 | 36.1 | 36.4 | 36.6 | 36.1 |
| 19 | 37.0 | 36.5 | 36.3 | 36.2 | 36.3 | 36.3 | 36.3 | 36.3 | 36.0 | 36.4 | 35.6 | 36.4 | 36.1 | 36.0 | 36.2 | 36.5 | 37.0 | 35.2 | 35.8 | | 36.2 |
| 20 | 36.8 | 36.2 | 36.2 | 36.2 | 36.3 | 36.1 | 36.1 | 36.3 | 36.4 | 36.4 | 36.2 | 36.4 | 36.0 | 36.0 | 36.4 | 36.4 | 36.0 | 36.1 | 36.4 | 37.1 | 36.4 |
| 21 | 36.7 | 35.8 | 36.5 | 36.3 | 36.1 | 36.3 | 35.9 | 36.4 | 35.8 | 36.1 | 36.4 | 36.1 | 35.9 | 36.1 | 35.8 | 35.9 | 35.8 | 36.4 | 36.6 | 35.9 | 36.0 |
| Summary | Body Temperature, °C | | | | | | | | | | | | | | | | | | | | |
| Average | 36.6 | 36.3 | 36.3 | 36.1 | 36.2 | 36.1 | 36.2 | 36.3 | 36.2 | 36.4 | 36.2 | 36.2 | 36.1 | 36.1 | 36.1 | 36.2 | 36.2 | 36.3 | 36.3 | 36.5 | 36.2 |
| Std Dev | 0.4 | 0.5 | 0.4 | 0.3 | 0.8 | 0.4 | 0.5 | 0.3 | 0.3 | 0.2 | 0.5 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.5 | 0.5 | 0.6 | 0.6 | 0.4 |
| Max | 37.0 | 37.6 | 37.3 | 36.7 | 38.7 | 36.9 | 37.4 | 37.1 | 37.0 | 36.8 | 37.1 | 36.8 | 36.8 | 36.9 | 36.9 | 36.7 | 37.0 | 37.0 | 37.8 | 38.1 | 36.8 |
| Min | 35.6 | 35.6 | 35.4 | 35.6 | 34.4 | 35.5 | 35.0 | 35.6 | 35.6 | 36.0 | 35.5 | 35.5 | 35.6 | 35.5 | 35.4 | 35.3 | 35.0 | 35.2 | 35.5 | 35.8 | 35.5 |

Units: °C

Table 6d-2
Vital Signs: Body Temperature

Blank = Not Obtained

| Subj \ Day | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 |
|------------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| 01 | 36.1 | 35.6 | 36.7 | 36.2 | 36.3 | 35.9 | 36.1 | 36.5 | 36.0 | 35.2 | 36.7 | 36.3 | 36.0 | 35.4 | 34.6 | 36.0 | 36.3 | 35.2 | 36.6 | 35.6 | 35.3 |
| 02 | 35.1 | 35.3 | 35.7 | 36.0 | 35.9 | 36.1 | 36.3 | 36.7 | 36.5 | 36.5 | 36.4 | 38.2 | | 38.3 | 36.9 | | | | | | |
| 03 | 36.8 | 36.6 | 36.7 | 36.4 | 36.7 | 35.8 | 36.5 | 36.6 | 36.7 | 36.4 | 36.2 | 36.7 | 36.2 | 36.8 | 36.5 | 36.6 | 36.5 | 36.7 | 35.7 | 36.6 | 36.1 |
| 04 | 37.0 | 36.7 | 37.1 | 36.7 | 37.2 | 37.0 | 36.7 | 37.2 | 36.8 | 36.9 | 36.7 | 36.8 | 37.0 | 36.9 | 36.6 | 36.6 | 36.8 | | | | |
| 05 | 36.1 | 36.1 | 34.8 | 35.3 | 35.0 | | 35.7 | 35.8 | | | | | | | | | | | | | |
| 06 | 36.6 | 36.4 | 36.4 | 36.7 | 36.1 | 37.0 | 37.0 | 36.5 | 37.0 | 36.6 | 36.7 | 36.7 | 37.0 | 37.1 | 36.0 | 35.9 | 36.9 | 36.9 | 36.4 | 36.0 | 36.9 |
| 07 | 36.6 | 36.7 | 36.4 | 35.5 | 36.2 | 36.6 | 36.9 | 39.9 | 36.7 | 35.5 | 36.3 | 36.7 | | | 36.6 | 36.5 | 36.6 | 35.6 | 36.2 | 35.6 | |
| 08 | | | | | | | | | | | | | | | | | | | | | |
| 09 | 36.3 | 36.0 | 36.3 | 37.0 | 36.4 | 35.8 | 36.0 | 36.4 | 36.2 | 36.2 | 36.4 | 36.1 | 36.5 | | 36.3 | 36.7 | 36.5 | 36.2 | 36.2 | 36.2 | 36.1 |
| 10 | 36.9 | 36.5 | 36.2 | 36.1 | 36.0 | 35.9 | 37.0 | 36.8 | 36.9 | 35.8 | 36.4 | 36.9 | 36.6 | 36.4 | 35.5 | 36.4 | 36.6 | 36.3 | 36.6 | 36.9 | 36.7 |
| 11 | 36.3 | 36.1 | 35.3 | 36.3 | 35.7 | 35.8 | 36.1 | 36.0 | 36.0 | 36.3 | 36.4 | 36.1 | 36.7 | 36.9 | 36.1 | 36.4 | 36.6 | 35.5 | 36.2 | 36.6 | 36.7 |
| 12 | 36.0 | 36.2 | 36.3 | 35.7 | 36.4 | 36.7 | 35.7 | 35.8 | 36.1 | 36.0 | 36.4 | 35.5 | 36.6 | 35.8 | 36.0 | 35.8 | 35.4 | 35.6 | 36.2 | 35.4 | 35.2 |
| 13 | 35.9 | 36.3 | 35.0 | 36.3 | 34.8 | 35.6 | 35.0 | 39.7 | 34.8 | 34.8 | 35.3 | 39.5 | 35.0 | 33.2 | 35.5 | 35.1 | 36.2 | 36.0 | 35.5 | 34.8 | 35.2 |
| 14 | 36.5 | 36.0 | 37.2 | 36.1 | 36.2 | 36.5 | 35.9 | 36.4 | 35.5 | 35.8 | 36.1 | 36.9 | 36.4 | 35.4 | 36.5 | 36.7 | 36.3 | 35.7 | 36.1 | 36.6 | |
| 15 | 35.3 | 35.0 | 35.7 | 35.8 | 35.3 | 36.0 | 36.0 | 35.8 | 36.0 | 34.7 | 34.6 | 36.1 | 35.3 | 34.1 | 35.1 | 35.1 | 35.4 | 36.0 | 35.0 | 35.4 | 36.0 |
| 16 | 36.3 | 36.0 | | 36.7 | 36.7 | 36.8 | 35.8 | 36.2 | 36.3 | | 36.1 | 36.2 | 36.9 | 36.1 | 35.9 | 36.1 | 36.2 | 36.0 | 36.1 | 35.8 | 36.3 |
| 17 | | | | | | | | | | | | | | | | | | | | | |
| 18 | 36.2 | 36.5 | | | 35.8 | 36.6 | 36.8 | | 36.5 | 35.8 | | 36.7 | 36.6 | 36.1 | 36.7 | | 36.5 | 35.3 | | 36.8 | 36.3 |
| 19 | 36.0 | 35.4 | 35.7 | 35.4 | 34.4 | 36.4 | 36.3 | 35.5 | 36.3 | 36.5 | 36.7 | 36.3 | 36.7 | 36.1 | 36.1 | 36.7 | 36.4 | 36.2 | 36.3 | 36.3 | 36.4 |
| 20 | 36.3 | 36.3 | 36.6 | | 36.3 | 36.5 | 35.5 | 36.7 | 36.8 | 36.0 | 36.6 | 36.5 | 36.1 | 36.0 | 36.0 | | | | 36.2 | 36.4 | 36.1 |
| 21 | 36.0 | 36.2 | | | 36.1 | 36.0 | 36.1 | 36.3 | | | | 36.1 | 36.3 | | 36.0 | 36.3 | | | 35.7 | 35.6 | 35.8 |
| Summary | | | | | | | | | | | | | | | | | | | | | |
| Average | 36.2 | 36.1 | 36.1 | 36.1 | 36.0 | 36.3 | 36.2 | 36.7 | 36.3 | 35.9 | 36.3 | 36.7 | 36.4 | 36.0 | 36.1 | 36.2 | 36.3 | 35.9 | 36.1 | 36.0 | 36.1 |
| Std Dev | 0.5 | 0.5 | 0.7 | 0.5 | 0.7 | 0.4 | 0.5 | 1.2 | 0.6 | 0.6 | 0.6 | 0.9 | 0.6 | 1.2 | 0.6 | 0.5 | 0.4 | 0.5 | 0.4 | 0.6 | 0.5 |
| Max | 37.0 | 36.7 | 37.2 | 37.0 | 37.2 | 37.0 | 37.0 | 39.9 | 37.0 | 36.9 | 36.7 | 39.5 | 37.0 | 38.3 | 36.9 | 36.7 | 36.9 | 36.9 | 36.6 | 36.9 | 36.9 |
| Min | 35.1 | 35.0 | 34.8 | 35.3 | 34.4 | 35.6 | 35.0 | 35.5 | 34.8 | 34.7 | 34.6 | 35.5 | 35.0 | 33.2 | 34.6 | 35.1 | 35.4 | 35.2 | 35.0 | 34.8 | 35.2 |

Units: °C

Table 6d-3
Vital Signs: Body Temperature

Blank = Not Obtained

| Subj \ Day | 42 | 43 | 44 | 45 | 48 | 51 | 54 | 57 | 72 | 180 |
|------------|------|------|------|------|------|------|------|------|------|------|
| 01 | 36.0 | 36.1 | 35.4 | 35.1 | 36.0 | 35.8 | 36.1 | 36.3 | 35.8 | 36.0 |
| 02 | | | | | | | | | | |
| 03 | 36.9 | 37.0 | 35.7 | 35.9 | 36.5 | 37.0 | 36.6 | 36.0 | 36.2 | 36.7 |
| 04 | | | | | | | | | | |
| 05 | | | | | | | | | | |
| 06 | | 36.2 | 36.4 | 36.4 | 36.6 | 36.3 | 36.6 | 36.4 | 36.7 | 36.7 |
| 07 | 37.2 | 35.8 | | | | 36.4 | 36.1 | 37.1 | 36.7 | 36.4 |
| 08 | | | | | | | | | | |
| 09 | | 36.1 | 36.3 | 36.5 | 36.2 | 36.7 | 36.2 | 36.5 | 36.2 | 36.8 |
| 10 | 36.7 | 36.6 | 36.4 | 36.6 | | 36.7 | 36.1 | | | |
| 11 | 36.4 | 36.5 | 36.4 | 36.6 | | | | | | |
| 12 | 35.8 | 35.8 | 35.6 | 35.8 | 36.0 | 35.0 | 35.5 | 35.0 | 36.0 | 35.3 |
| 13 | 36.0 | 35.0 | 35.5 | 36.0 | 36.6 | 35.9 | 35.8 | 36.6 | 36.6 | 35.4 |
| 14 | | | | | | | | | | |
| 15 | 36.1 | 36.0 | 36.4 | 35.2 | 35.8 | 35.5 | 36.5 | 36.2 | 36.7 | 35.1 |
| 16 | 36.2 | 36.6 | 36.9 | | | | | | 36.5 | 36.7 |
| 17 | | | | | | | | | | |
| 18 | | 36.1 | | 36.1 | 36.7 | 36.1 | 36.4 | 36.7 | 35.7 | |
| 19 | | 36.3 | 36.4 | | 37.0 | 36.1 | 36.4 | 35.9 | 36.6 | |
| 20 | 36.4 | 36.6 | 36.3 | 36.0 | 36.5 | 36.8 | 36.8 | 36.1 | | |
| 21 | 36.0 | 36.6 | 36.4 | 36.3 | 36.5 | 37.2 | 36.2 | 36.4 | 36.2 | |
| Summary | | | | | | | | | | |
| Average | 36.3 | 36.2 | 36.2 | 36.0 | 36.4 | 36.3 | 36.3 | 36.3 | 36.3 | 36.1 |
| Std Dev | 0.4 | 0.5 | 0.5 | 0.5 | 0.4 | 0.6 | 0.4 | 0.5 | 0.4 | 0.7 |
| Max | 37.2 | 37.0 | 36.9 | 36.6 | 37.0 | 37.0 | 36.8 | 37.1 | 36.7 | 36.8 |
| Min | 35.8 | 35.0 | 35.4 | 35.1 | 35.8 | 35.0 | 35.5 | 35.0 | 35.7 | 35.1 |

Figure 7: SD & Range Charts for Body Temperature, °C

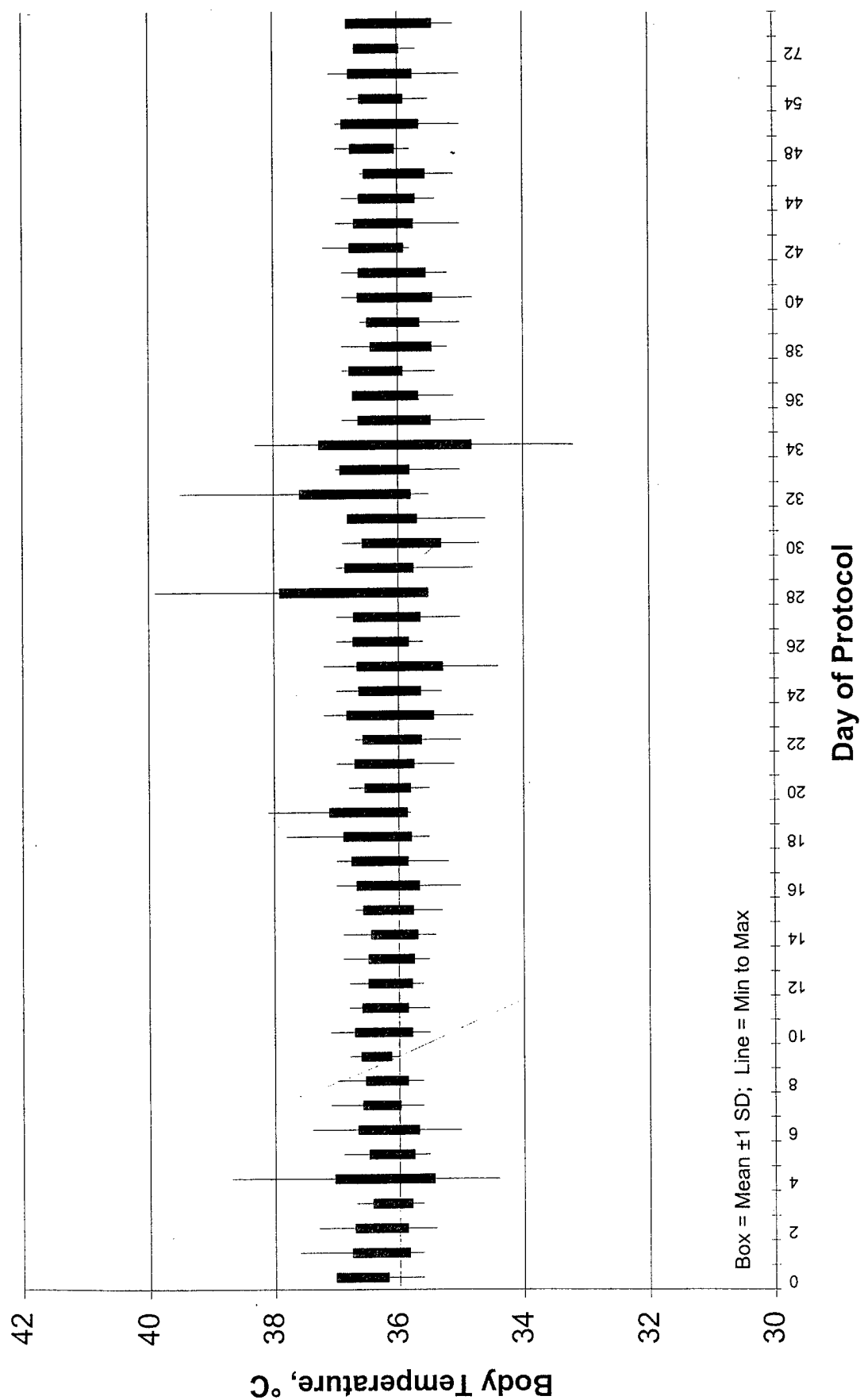
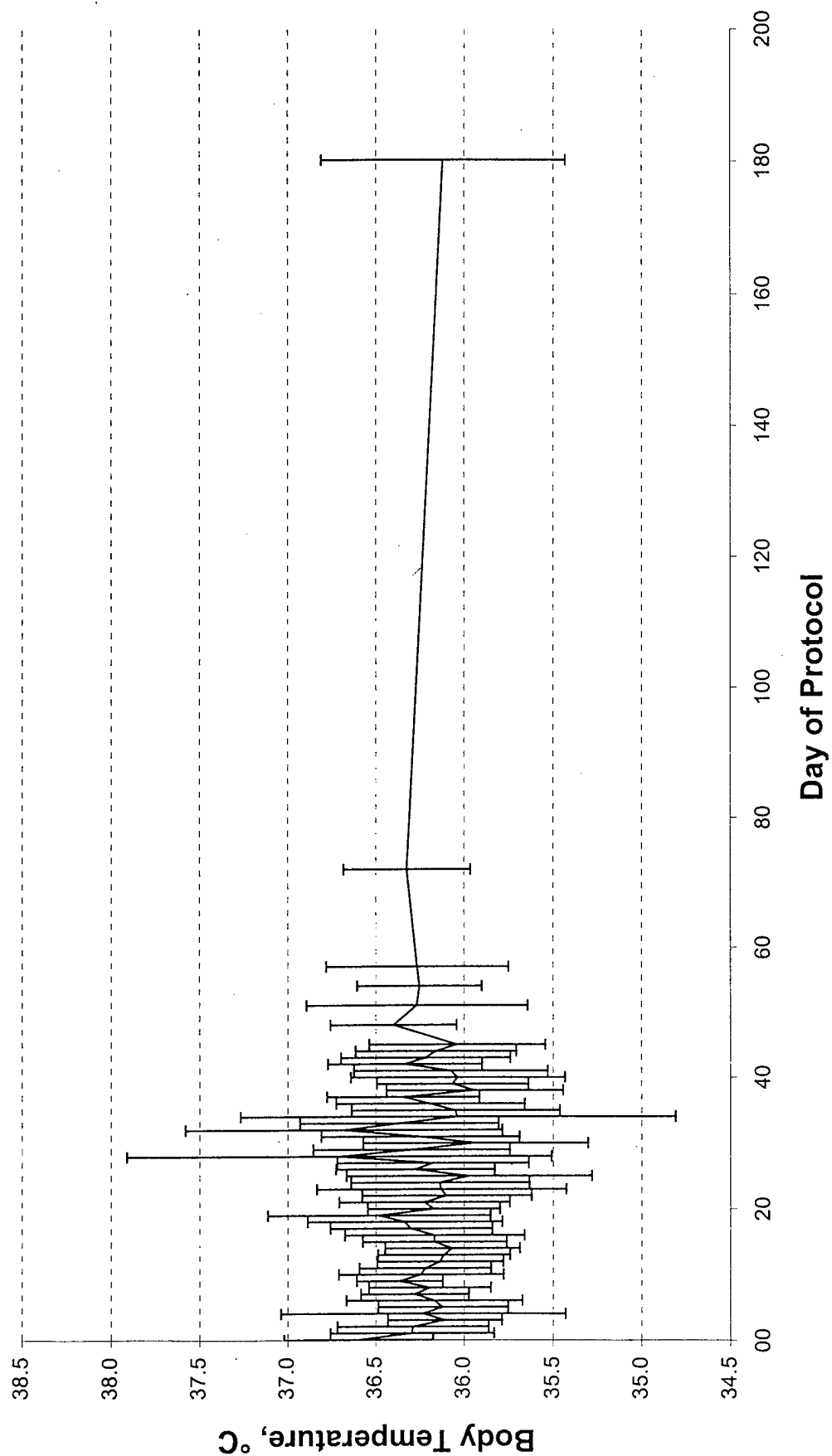


Figure 8: Body Temperature, °C



Blank = Not Obtained

Table 6e-1

Body Weight

Units: Pounds

| Subj \ Day | 00 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|------------|-----------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 01 | | | | | | | | | | | | | | | | | |
| 02 | | | | | | | | | | | | | | | | | |
| 03 | | | | | | | | | | | | | | | | | |
| 04 | | | | | | | | | 154 | 155 | 156 | 157 | 158 | 159 | 159 | 159.5 | 158 |
| 05 | | | | | | | | | 148 | 147 | 148 | 147 | 145 | 147 | 146 | 146 | 146 |
| 06 | | 169 | 166 | 166 | 169 | 170 | 170 | 170 | 169 | 170 | 169 | 168 | 170 | 170 | 169.5 | 170 | 169 |
| 07 | | 160 | 160 | 164 | 167 | 164 | 171 | 170 | 169 | 172 | 174 | 172 | 173 | 173 | 173 | 179 | 181 |
| 08 | | 127 | 125 | 125 | 125 | 125 | 126 | 125 | 125 | 125 | 125 | | | | | | |
| 09 | | 167 | 166 | 166 | 164 | 164 | 166 | 164 | 165 | 165.5 | 169 | 165 | 167 | 175 | 164 | 164 | 164 |
| 10 | | 167 | 161 | 163 | 161 | 161 | 161 | 162 | 164 | 164 | 164 | 164 | 165 | 166 | 165 | 165 | 165 |
| 11 | | 148 | 148 | 148 | 146 | 146 | 145 | 146 | 146 | 146 | 146 | 146 | 146 | 146 | 148 | 149 | 148.5 |
| 12 | | 181 | 180 | 182 | 182 | 182 | 182 | 182 | 185 | 184 | 183 | 184 | 184 | 184 | 182 | 182 | 183 |
| 13 | | 137 | 139 | 139 | 139 | 140 | 139 | 139 | 140 | 140 | 140 | 140 | 140 | 141 | 141 | 141 | 140 |
| 14 | | | 163 | 161 | 161 | 161 | 162 | 162 | 162 | 163 | 163 | 162 | 162 | 162 | 162 | 164 | 163 |
| 15 | | 154 | 153 | 153 | 154 | 153 | 153 | 154 | 152 | 152 | 152 | 152 | 153 | 152 | 152 | 152 | 152 |
| 16 | | 166 | 163 | 163 | 162 | 165 | 165 | 163.5 | 165 | 165 | 165 | 165 | 165 | 167 | 166 | 166 | 167.5 |
| 17 | | 168 | | | | | | | | | | | | | | | |
| 18 | | 145 | 145 | 145 | 145 | 145 | 145 | 144 | 148 | 148 | 150 | 144 | 150 | 150 | 152 | 151 | 152 |
| 19 | | 178 | 176 | 176 | 175 | 174 | 174 | 174 | 173 | 177 | 173 | 171 | 172 | 172 | 172 | 172 | 171 |
| 20 | | 170 | 170 | 172.5 | | 175 | 175 | 172 | 173 | 174 | 173 | 174 | 174.5 | 175 | 176 | 175 | 175 |
| 21 | 206 | 202 | 200 | 200 | 199 | 200 | 200 | 200 | 202 | 203 | 200 | 203 | 204 | 202 | 202 | 202 | 202 |
| Summary: | Body Weight, Lb | | | | | | | | | | | | | | | | |
| Average | 206.0 | 162.6 | 161.0 | 161.6 | 160.6 | 161.7 | 162.3 | 161.8 | 161.2 | 161.8 | 161.8 | 163.4 | 164.3 | 165.1 | 164.3 | 164.8 | 164.8 |
| Std Dev | | 18.6 | 18.0 | 18.2 | 18.6 | 18.4 | 18.5 | 18.4 | 17.9 | 18.4 | 17.6 | 16.2 | 16.2 | 15.9 | 15.3 | 15.5 | 15.8 |
| Max | 206 | 202 | 200 | 200 | 199 | 200 | 200 | 200 | 202 | 203 | 200 | 203 | 204 | 202 | 202 | 202 | 202 |
| Min | 206 | 127 | 125 | 125 | 125 | 125 | 126 | 125 | 125 | 125 | 125 | 140 | 140 | 141 | 141 | 141 | 140 |

Units: Pounds

Table 6e-2
Body Weight

Blank = Not Obtained

| Subj \ Day | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 01 | | | | | | | | | | | | | 150 | 148 | 151 | 152 |
| 02 | | | | | | | | | | | | 221 | 214 | 214 | 216 | |
| 03 | | | | | | | | | | | | | 148 | 148 | 148 | 148 |
| 04 | 160 | 159 | 159 | 159 | 159 | 159 | 163.5 | 169 | 169 | 163 | 162 | 163 | 163 | 148 | 148 | 148 |
| 05 | 146 | 146 | 144 | 145 | 144 | 145 | 148 | 150 | 150 | | | 150 | | | | |
| 06 | 170 | 170 | 170.5 | 172 | 173.5 | 171 | 171 | 172 | 175 | 174 | 173.5 | 173 | 172 | 172 | 172 | 172 |
| 07 | 179 | 178.5 | 178.5 | 181.5 | 179 | 178 | 179 | 181.5 | 182 | 180 | 176 | 177 | 178 | 180 | 180 | 178 |
| 08 | | | | | | | | | | | | | | | | |
| 09 | 164 | 166 | 165 | 167 | 166 | 166 | 169 | 166 | 163 | 162 | 164 | 164 | 164 | 167 | 167.5 | 168 |
| 10 | 165 | 168 | 166 | 168 | 169 | 168 | 168 | 168 | 168 | 168 | 168 | 168 | 168 | 167 | 170 | 169 |
| 11 | 147 | 147 | 147 | 147 | 148 | 147 | 150 | 148 | 150 | 148 | 150 | 150 | 154 | 152 | 149 | 150 |
| 12 | 183.7 | 185 | 183 | 182 | 183 | 180 | 185 | 185 | 184 | 184 | 184 | 184 | 182 | 182 | 184 | 183 |
| 13 | 140 | 140 | 141 | 140 | 140 | 142 | 140 | 141 | 141 | 142 | 142 | 140 | 141 | 142 | 140 | 139.5 |
| 14 | 166 | 165 | 163 | 164 | 164 | 167 | 168 | 167 | 167 | 167 | 165 | 165 | 165 | 166 | 165 | 167 |
| 15 | 152 | 152 | 152 | 153 | 153 | 153 | 154 | 154 | 154 | 156 | 157 | 154 | 158 | 156 | 156 | 151 |
| 16 | 167 | 167 | 167 | 168 | 168 | 168 | | 168 | 168 | 170 | 170 | 170 | 171 | | 170 | 171 |
| 17 | | | | | | | | | | | | | | | | |
| 18 | 152 | 151 | 152 | 152 | 152 | 153 | | | 152 | 152 | 151 | | 151.5 | 151 | | 152.5 |
| 19 | 171 | 172 | 173 | 173 | 172 | 171 | 172 | 179 | 176 | 178 | 175 | 178 | 177 | 180 | 176 | 178 |
| 20 | 175 | 178 | 178 | 177 | 179 | 180 | | 180 | 182.5 | 181 | 181 | 180 | 177 | 180 | 181 | 179 |
| 21 | 201 | 202 | 204 | 200 | 202 | 202 | | | 204 | 204 | | | 204 | 205 | | 205 |
| Summary: | | | | | | | | | | | | | | | | |
| Average | 164.9 | 165.4 | 165.2 | 165.5 | 165.7 | 165.6 | 164.0 | 166.3 | 167.8 | 168.6 | 165.6 | 169.1 | 168.8 | 168.1 | 167.1 | 165.4 |
| Std Dev | 15.7 | 16.2 | 16.4 | 15.8 | 16.2 | 15.6 | 13.4 | 13.5 | 16.2 | 15.9 | 12.3 | 19.0 | 18.7 | 20.5 | 18.9 | 16.9 |
| Max | 201 | 202 | 204 | 200 | 202 | 202 | 185 | 185 | 204 | 204 | 184 | 221 | 214 | 214 | 216 | 205 |
| Min | 140 | 140 | 141 | 140 | 140 | 142 | 140 | 141 | 141 | 142 | 142 | 140 | 141 | 142 | 140 | 140 |

Blank = Not Obtained

Table 6e-3

Body Weight

Units: Pounds

| Subj \ Day | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 48 | 51 | 54 | 57 |
|------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 01 | 150 | 150 | 149.5 | 150 | 150 | 151 | 149.5 | 150 | 149 | 149 | 148 | 149 | 152 | 149 | 148 | 147 | 147 |
| 02 | 206 | 206 | | | | | | | | | | | | | | | |
| 03 | 151 | 150 | 150 | 150 | 149.7 | 151 | 152 | 151.5 | 151 | 146 | 144 | 150 | 150 | 150 | 148 | 150 | 150 |
| 04 | 151 | 150 | 163 | 164 | 162 | | | | | | | | | | | | |
| 05 | | | | | | | | | | | | | | | | | |
| 06 | 173 | 171 | 170 | 171 | 172 | 172.5 | 172 | 172 | 169 | 169 | 172 | 172 | 172.5 | 172 | 171 | 170 | 173 |
| 07 | | | | | | | | | | | | | | | | | |
| 08 | | | | | | | | | | | | | | | | | |
| 09 | 168 | 166 | | | | | | | | | | | | | | | |
| 10 | 169 | 168 | 168 | 165 | 168 | 167 | 165 | 165 | 165 | 167 | 167 | 169 | 168 | | 170 | 169 | |
| 11 | 153 | 151 | 151 | 151 | 149 | 150 | 150 | 148 | 144 | 148 | 150 | 144 | 151 | | | | |
| 12 | 184 | 183 | 183 | 183 | 182 | 183 | 183 | 182 | 184 | 184 | 182 | 183 | 184 | 183 | 184.5 | 183 | 184 |
| 13 | 139 | 139 | 141 | 141 | 140 | 139 | 145 | 139 | 139 | 136 | 137 | 136 | 136 | 141 | 141 | 137 | 138 |
| 14 | 165 | 165 | 164 | 167 | 168 | 168 | 168 | 166 | 168 | | | | | | | | |
| 15 | 151 | 156 | 156 | 160 | 159 | 155 | 158 | 156 | 159 | 156 | 158 | 161 | 158 | 158 | 158 | 164 | 160 |
| 16 | | 174 | 172 | | 171 | 170 | 171 | 171 | 171 | 169 | 168 | 169 | | | | | |
| 17 | | | | | | | | | | | | | | | | | |
| 18 | 153 | 155 | 153 | | 151 | 145 | | 152 | 150 | 150 | | | 154 | 152 | 150 | 150 | 152 |
| 19 | 176 | 175 | | 177 | 178 | 176 | 179 | 178 | 175 | 173 | 173 | 177 | 181 | 174 | 179 | 174 | 178 |
| 20 | 177 | 178 | | | | 182 | 180 | 180 | | 179 | 179 | 181 | 180 | 181 | 182 | 180 | |
| 21 | 207 | 208 | 208 | 206 | | | 205 | 206 | 204 | 204 | | 204 | 204 | 205 | 204 | 208 | 210 |
| Summary: | | | | | | | | | | | | | | | | | |
| Average | 167.1 | 167.4 | 163.7 | 165.4 | 161.5 | 162.3 | 167.5 | 165.5 | 163.7 | 163.8 | 161.6 | 166.2 | 165.9 | 166.5 | 166.9 | 166.5 | 165.8 |
| Std Dev | 19.8 | 19.2 | 17.6 | 17.7 | 12.9 | 14.5 | 16.9 | 17.7 | 17.9 | 18.7 | 15.1 | 19.3 | 19.1 | 19.9 | 19.6 | 20.1 | 22.6 |
| Max | 207 | 208 | 208 | 206 | 182 | 183 | 205 | 206 | 204 | 204 | 182 | 204 | 204 | 205 | 204 | 208 | 210 |
| Min | 139 | 139 | 141 | 141 | 140 | 139 | 145 | 139 | 139 | 136 | 137 | 136 | 136 | 141 | 141 | 137 | 138 |

Units: Pounds

Table 6e-4
Body Weight

Blank = Not Obtained

| Subj \ Day | 72 | 180 |
|------------|-------|-------|
| 01 | 150 | 152 |
| 02 | | |
| 03 | 152 | 147 |
| 04 | | |
| 05 | | |
| 06 | 174 | 172 |
| 07 | | |
| 08 | | |
| 09 | | |
| 10 | | |
| 11 | | |
| 12 | 183 | 192 |
| 13 | 137 | 134 |
| 14 | | |
| 15 | 155 | |
| 16 | | |
| 17 | | |
| 18 | | |
| 19 | 178 | |
| 20 | | |
| 21 | 204 | |
| Summary: | | |
| Average | 166.6 | 159.4 |
| Std Dev | 21.9 | 22.8 |
| Max | 204 | 192 |
| Min | 137 | 134 |

Dec. 17, 1998

Figure 9: SD & Range Charts for Body Weight, Lb

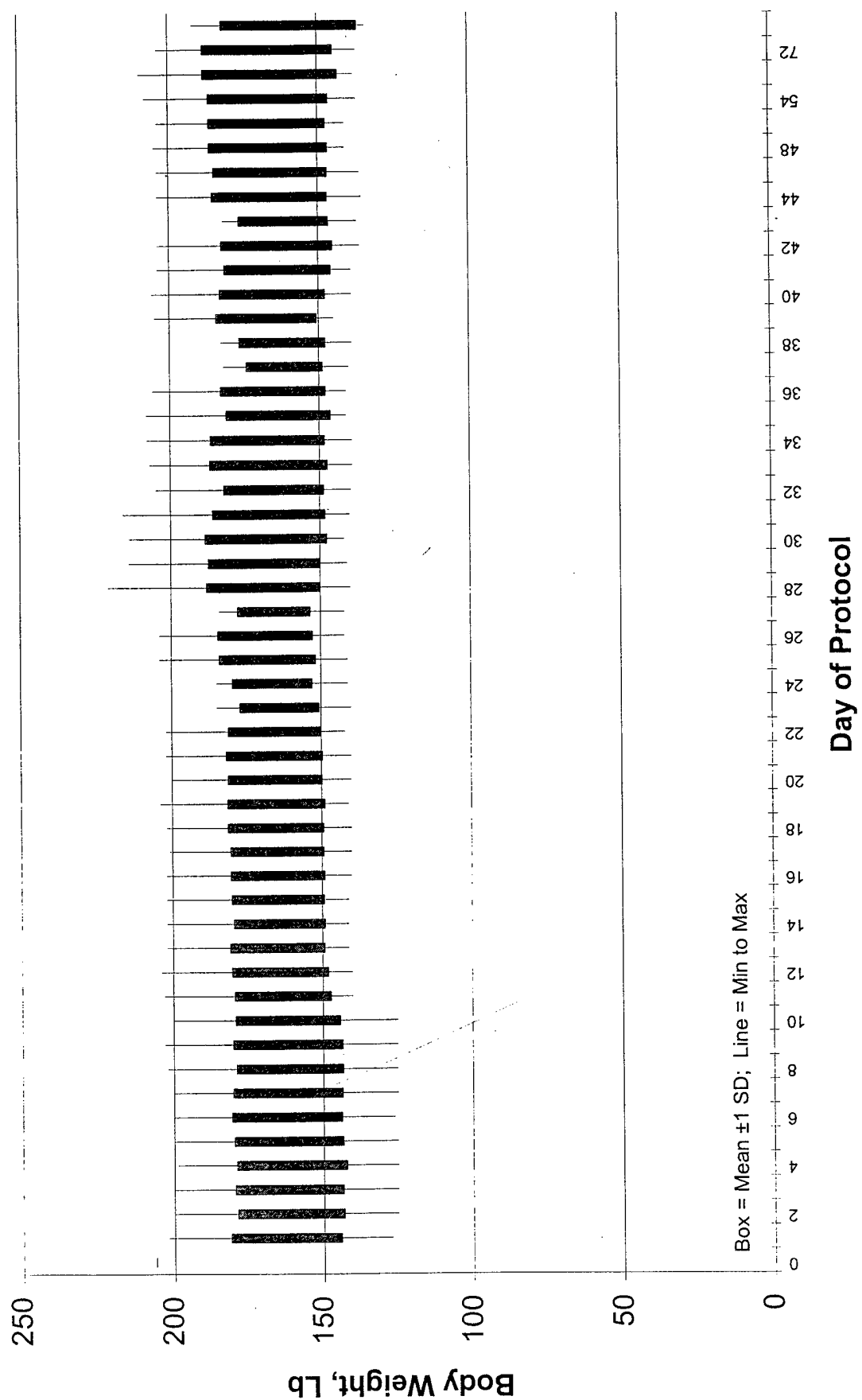


Figure 10: Body Weight, Lb

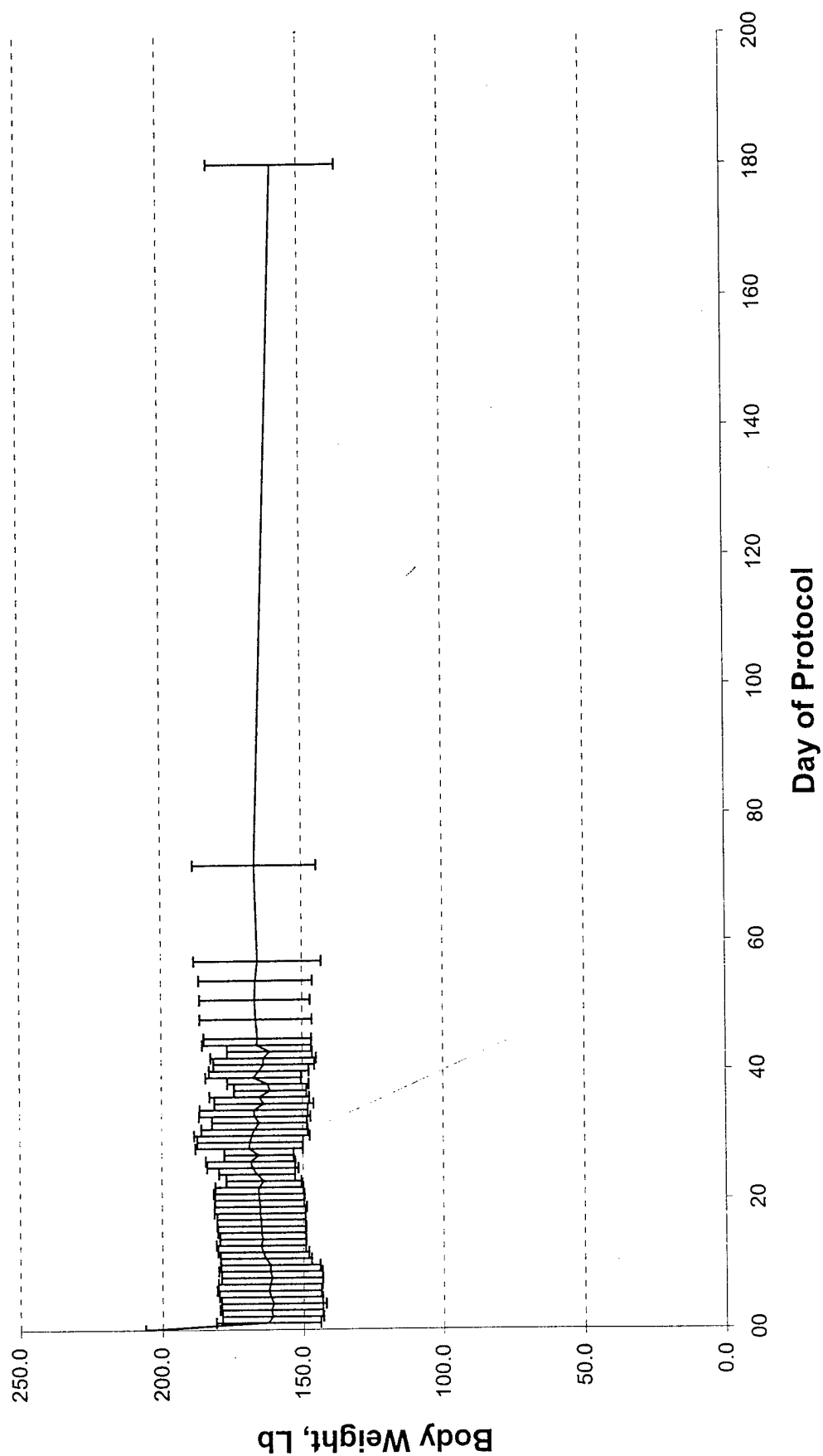


Table 7
Beta-HCG

| Subject | SCR | DAY 0 | DAY 28 | DAY 54 | DAY 84 | DAY 112 | DAY 140 | DAY 168 |
|---------|-----|-------|--------|--------|--------|---------|---------|---------|
| 03 | - | - | - | - | - | - | - | - |
| 10 | - | - | - | - | - | - | - | - |
| 11 | - | - | - | - | - | - | - | - |

Blank = Not Obtained

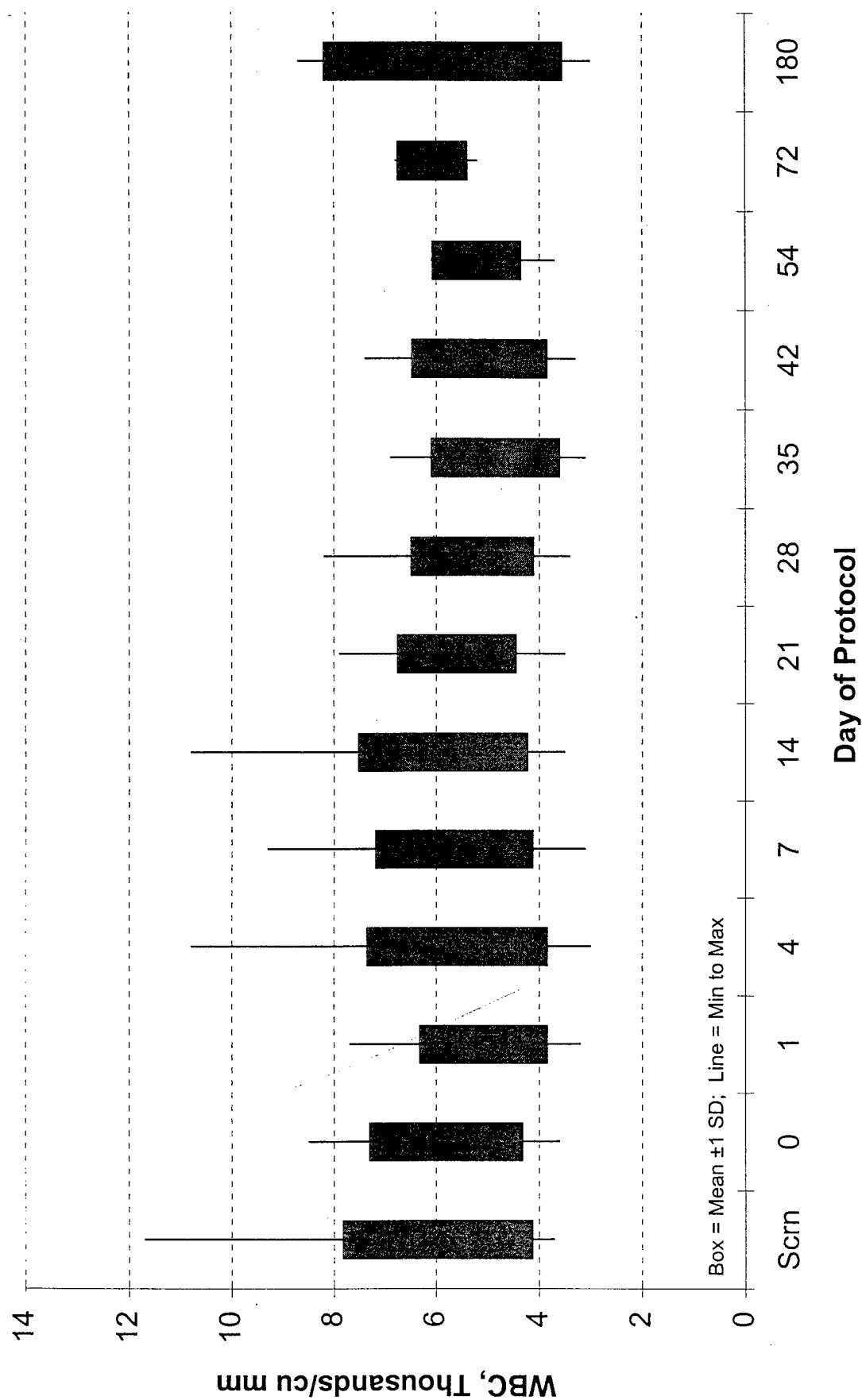
Thousands/cu mm

Table 8a
WBC

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|----------------------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 1 | 8.1 | 8.5 | 6.4 | 6.2 | 7.0 | 7.0 | 5.1 | 5.6 | 5.1 | 7.4 | 5.7 | 6.8 | 6.0 |
| 2 | 4.5 | 5.0 | 3.3 | 4.6 | 4.9 | 5.5 | 5.7 | 5.2 | 3.2 | | | | |
| 3 | 4.5 | 5.2 | 5.2 | 4.1 | 5.7 | 4.5 | 3.5 | 3.5 | 3.4 | 4.0 | 3.7 | 5.9 | 3.0 |
| 4 | 7.5 | 7.2 | 6.2 | 6.8 | 6.0 | 7.1 | 7.0 | 6.3 | 6.6 | 6.4 | | | |
| 5 | 4.3 | 3.7 | 3.2 | 3.0 | 3.1 | 3.5 | 3.8 | 3.4 | 3.1 | | | | |
| 6 | 4.3 | 4.1 | 4.0 | 4.9 | 4.0 | 4.2 | 4.4 | 4.4 | 3.9 | 4.0 | 3.7 | 6.4 | 5.8 |
| 7 | 5.3 | 5.0 | 3.9 | 4.3 | 4.5 | 5.7 | 6.0 | 4.5 | | 5.0 | 6.1 | | |
| 8 | 3.7 | 3.6 | 5.0 | 5.4 | 4.3 | | | | | | | | |
| 9 | 5.5 | 6.4 | 6.6 | 8.0 | 7.2 | 6.7 | 6.2 | 5.7 | 6.8 | 7.0 | 5.8 | | |
| 10 | 5.3 | 4.4 | 4.7 | 4.5 | 4.8 | 4.5 | 5.2 | 5.2 | 4.6 | 4.4 | 5.0 | | |
| 11 | 8.8 | 5.6 | 4.1 | 4.5 | 5.4 | 6.0 | 7.9 | 6.3 | | 6.3 | | | |
| 12 | 6.1 | 4.5 | 3.8 | 4.1 | 4.1 | 4.0 | 4.2 | 3.7 | 4.3 | 3.9 | 4.3 | | |
| 13 | 5.6 | 6.0 | 5.0 | 5.1 | 5.8 | 5.5 | 5.3 | 4.0 | 4.6 | 3.7 | 6.0 | | |
| 14 | 11.7 | 8.1 | 7.7 | 7.7 | 9.3 | 6.7 | 7.0 | 8.2 | | | | | |
| 15 | 6.4 | 6.0 | 6.1 | 6.1 | 5.4 | 5.4 | 5.0 | 6.4 | 6.9 | 6.1 | 5.8 | | 8.7 |
| 16 | 5.7 | 6.5 | 5.6 | 5.8 | 5.3 | 5.6 | 5.7 | 5.9 | 6.0 | 5.5 | | | |
| 17 | 6.7 | 8.4 | 6.0 | | | | | | | | | | |
| 18 | 4.5 | 4.6 | 4.3 | 5.1 | 5.7 | 6.5 | 6.0 | 5.0 | 4.9 | 3.8 | 4.6 | | |
| 19 | 5.6 | 7.3 | 5.7 | 10.8 | 8.8 | 10.8 | 7.0 | 6.2 | 5.2 | 6.4 | 5.6 | | |
| 20 | 4.7 | 5.1 | 3.6 | 4.4 | 5.1 | 4.8 | 5.2 | 5.8 | 3.6 | 3.3 | 6.1 | | |
| 21 | 6.7 | 6.9 | 6.3 | 6.6 | 6.6 | 7.6 | 6.2 | 5.4 | 5.4 | 5.4 | 5.4 | 5.2 | |
| Summary: | WBC, Thousands/cu mm | | | | | | | | | | | | |
| Average | 6.0 | 5.8 | 5.1 | 5.6 | 5.7 | 5.9 | 5.6 | 5.3 | 4.9 | 5.2 | 5.2 | 6.1 | 5.9 |
| Std Dev | 1.9 | 1.5 | 1.2 | 1.8 | 1.5 | 1.7 | 1.2 | 1.2 | 1.3 | 1.3 | 0.9 | 0.7 | 2.3 |
| Max | 11.7 | 8.5 | 7.7 | 10.8 | 9.3 | 10.8 | 7.9 | 8.2 | 6.9 | 7.4 | 6.1 | 6.8 | 8.7 |
| Min | 3.7 | 3.6 | 3.2 | 3.0 | 3.1 | 3.5 | 3.5 | 3.4 | 3.1 | 3.3 | 3.7 | 5.2 | 3.0 |

Figure 11: SD & Range Charts for WBC, Thousands/cu mm



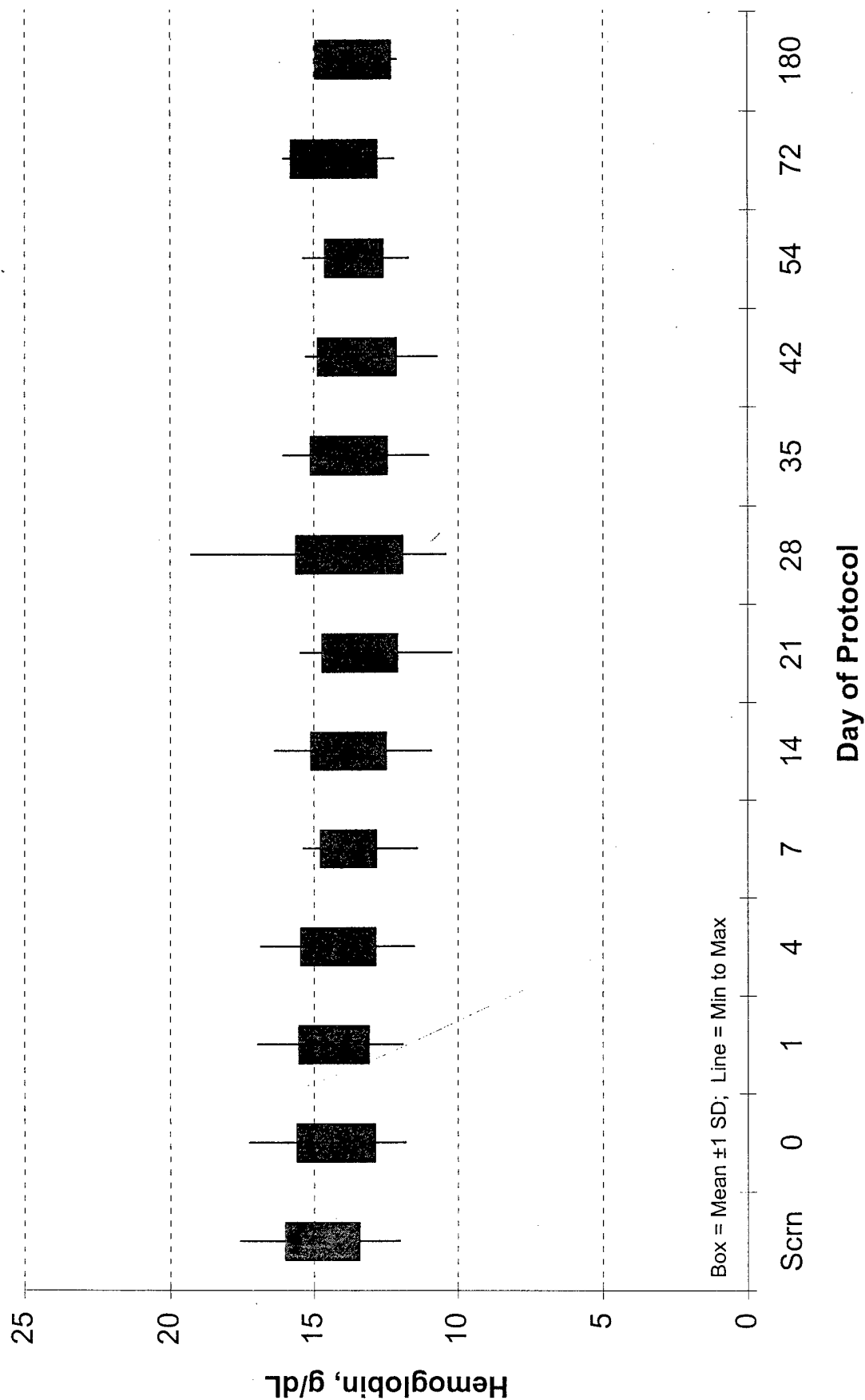
Units: g/dL

Table 8b
Hemoglobin

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 15.8 | 17.3 | 17 | 14.8 | 14.9 | 14.2 | 15.5 | 13.2 | 13.9 | 13.9 | 14 | 14.7 | 14.3 |
| 02 | 15.3 | 16.3 | 14.1 | 15.4 | 15.1 | 16.4 | 15 | 15 | 14.9 | 14.5 | | | |
| 03 | 14.1 | 13.3 | 15.2 | 12.9 | 13.2 | 14.5 | 12.5 | 13.3 | 11.6 | 12.5 | 12.3 | 12.2 | 12.1 |
| 04 | 14.9 | 14.8 | 15.4 | 14.8 | 14.2 | 14.1 | 13.6 | 13.9 | 13.6 | | | | |
| 05 | 14.8 | 14 | 13.7 | 13.5 | 13.1 | 13.2 | 13.6 | 14.1 | | | | | |
| 06 | 14.2 | 14.3 | 14.2 | 13.8 | 13.5 | 13.8 | 13.1 | 13.5 | 14 | 13.6 | 13.2 | 13.4 | 14.5 |
| 07 | 14.2 | 12.7 | 12.4 | 13 | 13.3 | 12.8 | 12.8 | 12.2 | | 12 | 12.7 | | |
| 08 | 13.9 | 13.7 | 13.7 | 13.5 | 13.2 | | | | | | | | |
| 09 | 14.2 | 14.3 | 14.2 | 14.8 | 13.8 | 13.7 | 12.9 | 13.8 | 12 | 13.9 | 13.5 | | |
| 10 | 12 | 11.8 | 11.9 | 11.5 | 11.4 | 11.4 | 10.2 | 10.8 | 11 | 11.4 | 11.7 | | |
| 11 | 12 | 11.9 | 12 | 11.7 | 12.1 | 10.9 | 11.3 | 10.4 | | 10.7 | | | |
| 12 | 15.6 | 13 | 14.2 | 13.8 | 14 | 13 | 13.2 | 13.8 | 14.1 | 13.9 | 13.8 | | |
| 13 | 14.9 | 14.4 | 14.7 | 14 | 13.6 | 13.4 | 13.8 | 13.6 | 13.9 | 14.7 | 13.4 | | |
| 14 | 15.4 | 14 | 14.2 | 15.1 | 13.8 | 15.3 | 15 | 14.4 | 14.8 | | | | |
| 15 | 17.6 | 15.9 | 15.4 | 15.8 | 14.4 | 14.9 | 13 | 15.8 | 16.1 | 14.8 | 14.5 | | |
| 16 | 14.7 | 13.8 | 13.9 | 14.4 | 13.8 | 12.9 | 13.2 | 13.3 | 13.6 | 12.3 | | | |
| 17 | 16.2 | 16.1 | 16 | | | | | | | | | | |
| 18 | 13 | 13.4 | 13.6 | 13.5 | 13.4 | 13.2 | 12.6 | 12.4 | 12.7 | 12.8 | 13.1 | | |
| 19 | 15.1 | 14.5 | 15 | 15.5 | 15.4 | 15.3 | 14.8 | 14.7 | 14.8 | 14.7 | 14.5 | | |
| 20 | 15.9 | 14.4 | 15 | 16.9 | 14.9 | 14.6 | 15.1 | 19.3 | 15 | 14.9 | 15.4 | 16.1 | |
| 21 | 15.2 | 15.1 | 14.8 | 14.5 | 14.9 | 14.6 | 13.5 | 14.2 | 14.5 | 15.3 | 14.7 | 15.1 | |
| Summary: | Hemoglobin, g/dL | | | | | | | | | | | | |
| Average | 14.7 | 14.2 | 14.3 | 14.2 | 13.8 | 13.8 | 13.4 | 13.8 | 13.8 | 13.5 | 13.6 | 14.3 | 13.6 |
| Std Dev | 1.3 | 1.4 | 1.2 | 1.3 | 1.0 | 1.3 | 1.3 | 1.9 | 1.4 | 1.4 | 1.0 | 1.5 | 1.3 |
| Max | 18 | 17 | 17 | 17 | 15 | 16 | 16 | 19 | 16 | 15 | 15 | 16 | 15 |
| Min | 12 | 12 | 12 | 12 | 11 | 11 | 10 | 10 | 11 | 11 | 12 | 12 | 12 |

Figure 12: SD & Range Charts for Hemoglobin, g/dL



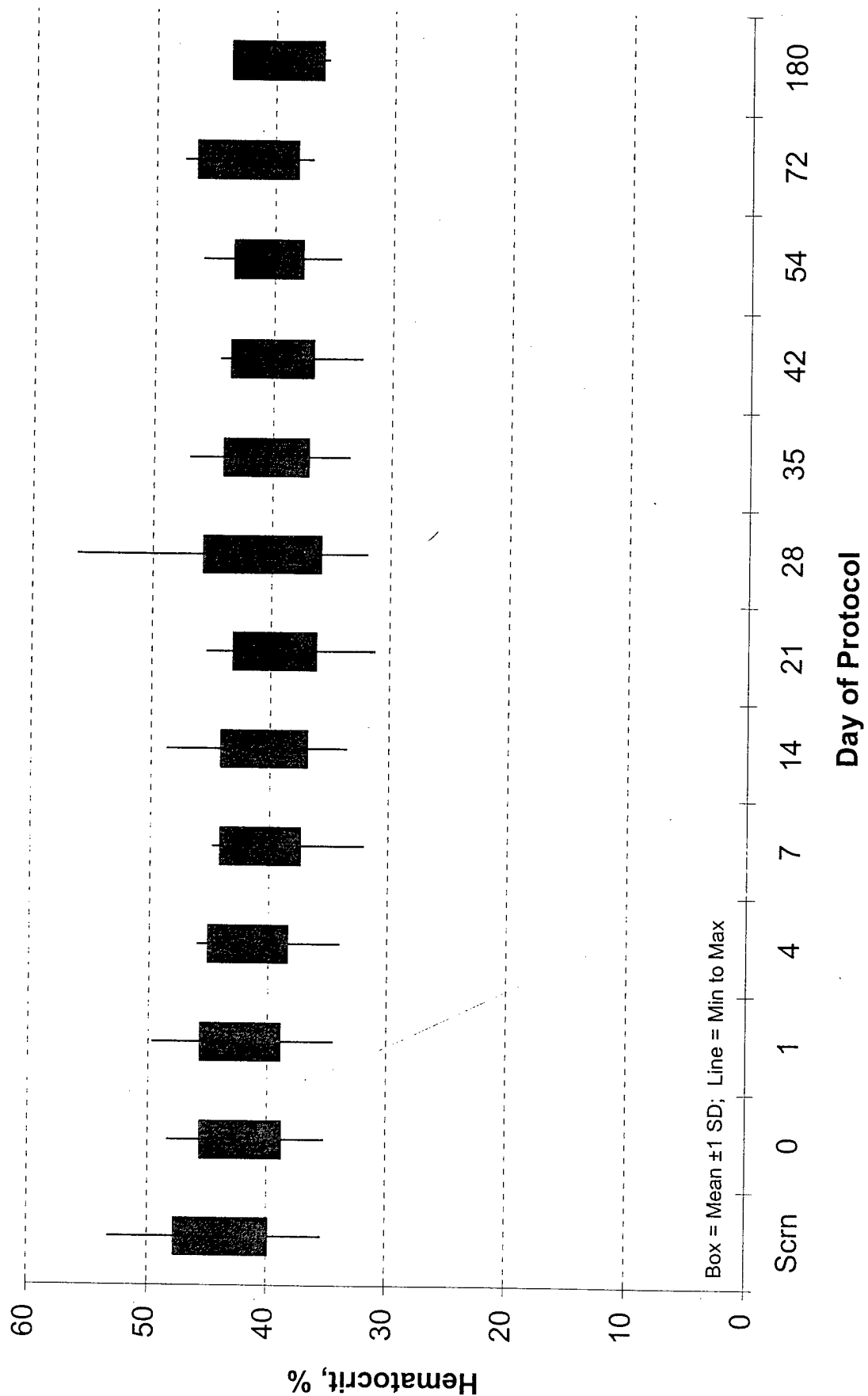
Units: %

Table 8c
Hematocrit

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|---------------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 1 | 46.5 | 48.0 | 49.7 | 43.5 | 43.0 | 41.0 | 45.4 | 38.8 | 40.3 | 40.9 | 41.8 | 44.5 | 43.0 |
| 2 | 45.3 | 46.0 | 41.9 | 45.2 | 44.3 | 48.7 | 44.4 | 43.3 | 43.4 | 43.3 | | | |
| 3 | 41.8 | 40.1 | 44.6 | 37.6 | 39.7 | 42.2 | 37.6 | 38.7 | 34.5 | 37.0 | 36.8 | 36.8 | 35.5 |
| 4 | 47.4 | 42.9 | 45.2 | 43.2 | 42.1 | 41.0 | 39.8 | 41.8 | 40.5 | | | | |
| 5 | 41.6 | 42.2 | 41.2 | 40.6 | 39.5 | 39.0 | 41.4 | 43.2 | | | | | |
| 6 | 42.0 | 41.2 | 41.7 | 40.5 | 39.4 | 39.9 | 37.8 | 38.9 | 39.7 | 40.0 | 39.7 | 39.3 | 41.0 |
| 7 | 43.0 | 38.3 | 37.9 | 39.3 | 36.8 | 37.0 | 38.7 | 38.9 | | 36.8 | 39.1 | | |
| 8 | 42.9 | 41.8 | 40.8 | 41.3 | 39.5 | | | | | | | | |
| 9 | 42.9 | 42.8 | 41.7 | 44.5 | 36.4 | 39.9 | 39.3 | 42.5 | 36.2 | 42.2 | 40.3 | | |
| 10 | 35.4 | 35.3 | 35.8 | 34.3 | 32.0 | 33.5 | 31.2 | 33.4 | 33.5 | 34.6 | 34.4 | | |
| 11 | 36.5 | 35.2 | 34.5 | 34.0 | 36.2 | 33.6 | 35.4 | 31.9 | | 32.5 | | | |
| 12 | 47.9 | 40.0 | 43.4 | 43.0 | 42.9 | 39.4 | 40.0 | 40.0 | 40.5 | 40.6 | 40.4 | | |
| 13 | 44.9 | 42.5 | 43.2 | 40.9 | 40.0 | 37.8 | 39.4 | 38.6 | 40.6 | 42.5 | 40.2 | | |
| 14 | 44.5 | 41.7 | 41.4 | 43.9 | 44.3 | 44.1 | 44.1 | 42.4 | 44.2 | | | | |
| 15 | 53.3 | 46.8 | 43.9 | 46.0 | 43.9 | 42.2 | 37.0 | 45.0 | 47.0 | 43.5 | 41.8 | | |
| 16 | 43.5 | 42.6 | 43.0 | 42.8 | 42.3 | 38.4 | 39.0 | 39.7 | 41.3 | 37.6 | | | |
| 17 | 48.3 | 48.4 | 47.4 | | | | | | | | | | |
| 18 | 38.9 | 40.2 | 40.4 | 40.8 | 40.5 | 40.8 | 37.0 | 37.4 | 38.4 | 39.6 | 39.6 | | |
| 19 | 45.5 | 44.1 | 44.0 | 45.3 | 44.8 | 45.0 | 44.1 | 43.0 | 43.9 | 42.9 | 42.7 | | |
| 20 | 45.5 | 42.4 | 43.6 | 45.5 | 44.3 | 43.3 | 43.5 | 56.3 | 44.0 | 43.5 | 46.0 | 47.6 | |
| 21 | 42.9 | 43.8 | 42.8 | 41.9 | 43.3 | 42.8 | 38.9 | 41.4 | 41.0 | 44.5 | 43.8 | 43.3 | |
| Summary: | Hematocrit, % | | | | | | | | | | | | |
| Average | 43.8 | 42.2 | 42.3 | 41.7 | 40.8 | 40.5 | 39.7 | 40.8 | 40.6 | 40.1 | 40.5 | 42.3 | 39.8 |
| Std Dev | 4.0 | 3.5 | 3.4 | 3.4 | 3.4 | 3.7 | 3.5 | 5.0 | 3.6 | 3.5 | 2.9 | 4.3 | 3.9 |
| Max | 53.3 | 48.4 | 49.7 | 46.0 | 44.8 | 48.7 | 45.4 | 56.3 | 47.0 | 44.5 | 46.0 | 47.6 | 43.0 |
| Min | 35.4 | 35.2 | 34.5 | 34.0 | 32.0 | 33.5 | 31.2 | 31.9 | 33.5 | 32.5 | 34.4 | 36.8 | 35.5 |

Figure 13: SD & Range Charts for Hematocrit, %



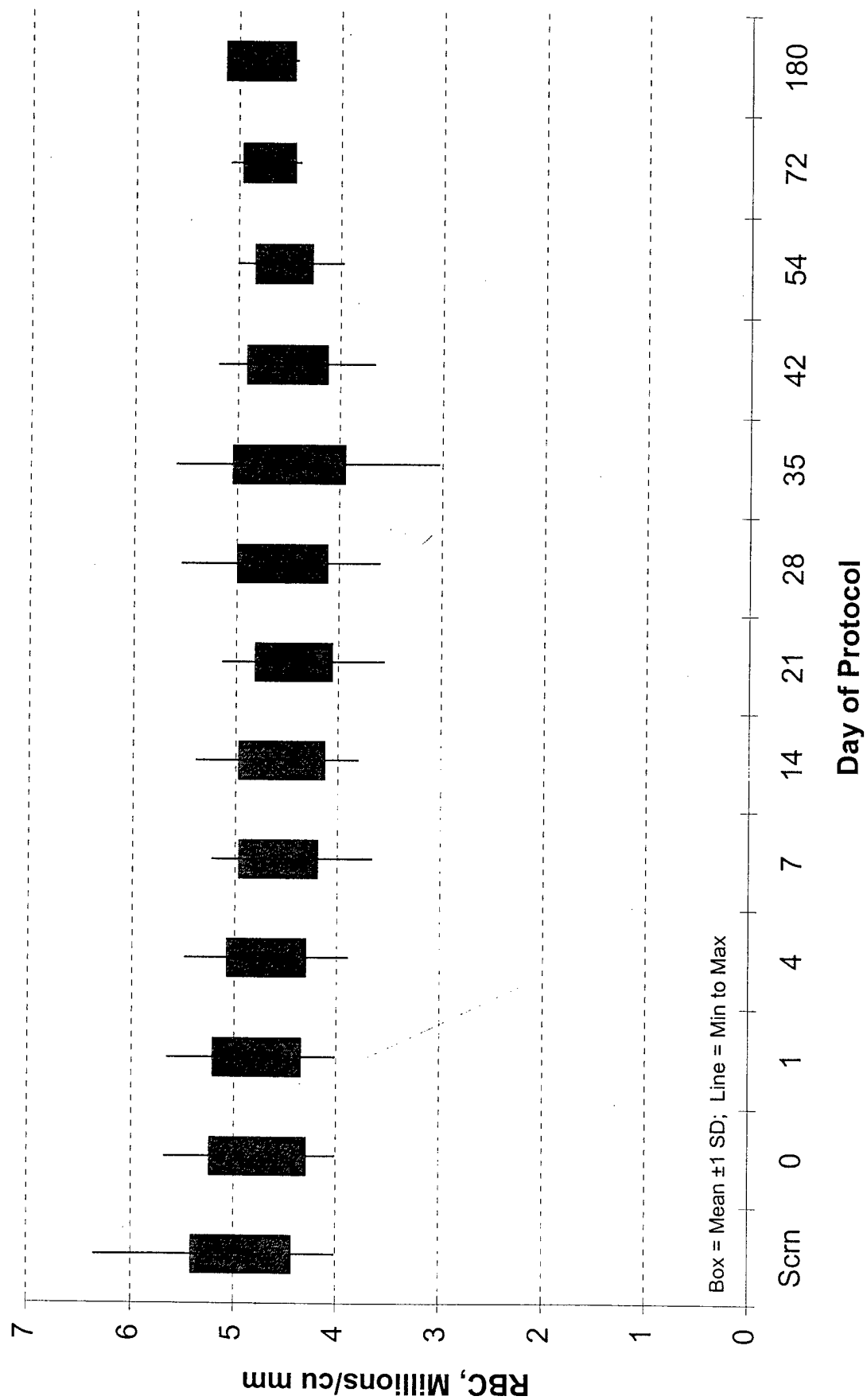
Units: Million / cu mm

Table 8d
RBC

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|---------------------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 1 | 5.29 | 5.49 | 5.66 | 4.93 | 4.94 | 4.71 | 5.14 | 4.42 | 4.60 | 4.63 | 4.74 | 5.08 | 5.09 |
| 2 | 4.99 | 5.18 | 4.67 | 5.01 | 4.92 | 5.39 | 4.92 | 4.90 | 4.94 | 4.87 | | | |
| 3 | 4.76 | 4.57 | 5.12 | 4.31 | 4.49 | 4.90 | 4.33 | 4.50 | 3.03 | 4.37 | 4.28 | 4.39 | 4.42 |
| 4 | 5.30 | 4.76 | 4.99 | 4.84 | 4.63 | 4.58 | 4.43 | 4.61 | 4.50 | | | | |
| 5 | 4.78 | 4.85 | 4.72 | 4.67 | 4.59 | 4.56 | 4.74 | 4.98 | | | | | |
| 6 | 4.86 | 4.80 | 4.81 | 4.69 | 4.85 | 4.65 | 4.35 | 4.48 | 4.58 | 4.64 | 4.59 | 4.54 | 4.86 |
| 7 | 4.77 | 4.32 | 4.18 | 4.36 | 3.98 | 4.15 | 4.16 | 4.31 | | 4.21 | 4.47 | | |
| 8 | 5.01 | 4.94 | 4.83 | 4.85 | 4.71 | | | | | | | | |
| 9 | 4.88 | 4.90 | 4.81 | 5.03 | 4.15 | 4.57 | 4.46 | 4.84 | 4.15 | 4.79 | 4.55 | | |
| 10 | 4.01 | 4.01 | 4.07 | 3.91 | 3.66 | 3.82 | 3.55 | 3.82 | 3.85 | 3.99 | 3.97 | | |
| 11 | 4.18 | 4.01 | 4.01 | 3.89 | 4.15 | 3.80 | 3.98 | 3.60 | | 3.66 | | | |
| 12 | 4.99 | 4.18 | 4.54 | 4.50 | 4.47 | 4.15 | 4.16 | 4.22 | 4.34 | 4.28 | 4.27 | | |
| 13 | 5.01 | 4.76 | 4.82 | 4.52 | 4.42 | 4.25 | 4.39 | 4.30 | 4.48 | 4.71 | 4.42 | | |
| 14 | 4.71 | 4.51 | 4.51 | 4.75 | 4.68 | 4.72 | 4.72 | 4.56 | 4.75 | | | | |
| 15 | 6.36 | 5.68 | 5.37 | 5.49 | 5.22 | 5.08 | 4.51 | 5.10 | 5.60 | 5.19 | 5.01 | | |
| 16 | 4.91 | 4.75 | 4.82 | 4.79 | 4.65 | 4.32 | 4.46 | 4.44 | 4.63 | 4.25 | | | |
| 17 | 5.61 | 5.65 | 5.54 | | | | | | | | | | |
| 18 | 4.49 | 4.70 | 4.73 | 4.73 | 4.70 | 4.73 | 4.43 | 4.40 | 4.45 | 4.51 | 4.64 | | |
| 19 | 5.27 | 5.01 | 5.09 | 5.28 | 5.23 | 5.18 | 5.12 | 4.99 | 5.08 | 4.97 | 4.97 | | |
| 20 | 4.47 | 4.19 | 4.31 | 4.62 | 4.34 | 4.22 | 4.27 | 5.54 | 4.35 | 4.30 | 4.57 | 4.77 | |
| 21 | 4.76 | 4.79 | 4.72 | 4.61 | 4.76 | 4.66 | 4.20 | 4.49 | 4.57 | 4.90 | 4.74 | 4.74 | |
| Summary: | RBC, Millions/cu mm | | | | | | | | | | | | |
| Average | 4.92 | 4.76 | 4.78 | 4.69 | 4.58 | 4.55 | 4.44 | 4.55 | 4.49 | 4.52 | 4.56 | 4.70 | 4.79 |
| Std Dev | 0.49 | 0.48 | 0.44 | 0.39 | 0.39 | 0.43 | 0.38 | 0.45 | 0.55 | 0.40 | 0.29 | 0.26 | 0.34 |
| Max | 6.36 | 5.68 | 5.66 | 5.49 | 5.23 | 5.39 | 5.14 | 5.54 | 5.60 | 5.19 | 5.01 | 5.08 | 5.09 |
| Min | 4.01 | 4.01 | 4.01 | 3.89 | 3.66 | 3.80 | 3.55 | 3.60 | 3.03 | 3.66 | 3.97 | 4.39 | 4.42 |

Figure 14: SD & Range Charts for RBC, Millions/cu mm



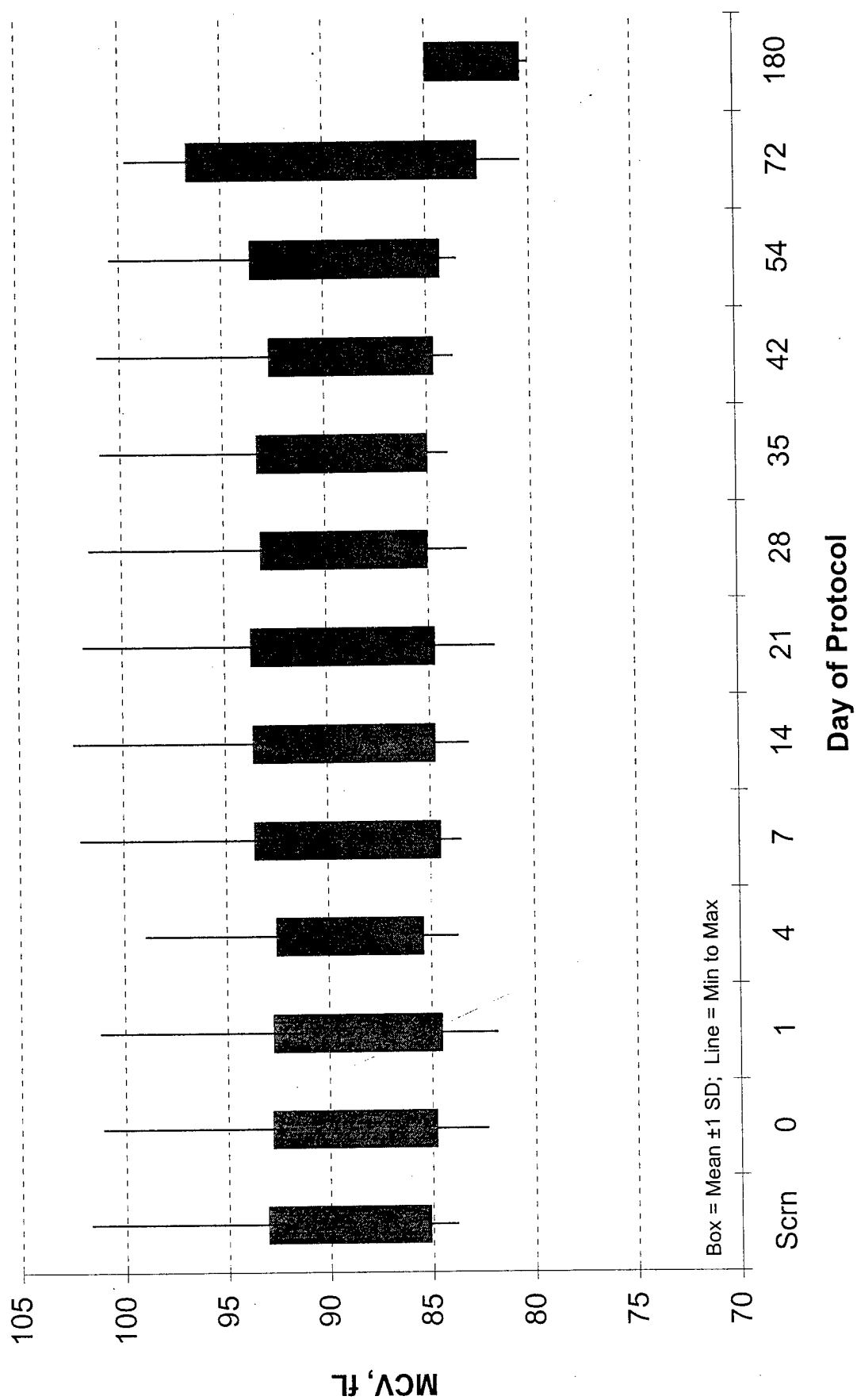
Units: Femtoliters

Table 8e
MCV

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|---------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | 88.0 | 87.0 | 87.8 | 88.2 | 87.0 | 86.9 | 88.2 | 87.5 | 87.6 | 88.2 | 88.1 | 87.5 | 84.0 |
| 02 | 90.7 | 89.0 | 89.7 | 90.1 | 90.0 | 90.3 | 90.2 | 88.3 | 87.8 | 88.9 | | | |
| 03 | 87.8 | 87.8 | 86.9 | 87.2 | 88.4 | 86.0 | 86.9 | 85.8 | 85.6 | 84.8 | 85.9 | 83.8 | 80.0 |
| 04 | 89.3 | 90.0 | 90.6 | 89.5 | 90.9 | 89.0 | 89.9 | 90.7 | 90.0 | | | | |
| 05 | 87.0 | 86.8 | 87.2 | 86.8 | 86.0 | 85.0 | 87.3 | 86.6 | | | | | |
| 06 | 86.4 | 85.8 | 86.7 | 86.0 | 86.0 | 85.7 | 87.0 | 86.8 | 86.7 | 86.3 | 86.6 | 80.4 | 84.0 |
| 07 | 90.0 | 90.3 | 90.7 | 90.1 | 90.0 | 88.6 | 89.0 | 89.7 | | 87.4 | 87.4 | | |
| 08 | 85.6 | 84.6 | 84.5 | 85.1 | 84.0 | | | | | | | | |
| 09 | 87.9 | 87.2 | 86.7 | 88.3 | 83.5 | 87.1 | 88.2 | 87.7 | 87.3 | 88.0 | 88.6 | | |
| 10 | 88.3 | 88.0 | 88.0 | 87.7 | 87.6 | 87.5 | 87.7 | 87.4 | 86.9 | 86.6 | 86.5 | | |
| 11 | 87.3 | 87.6 | 86.0 | 87.4 | 87.2 | 88.5 | 88.8 | 88.5 | | 88.8 | | | |
| 12 | 95.9 | 95.4 | 95.6 | 95.6 | 96.0 | 95.8 | 96.2 | 94.2 | 94.7 | 93.0 | 94.7 | 94.6 | |
| 13 | 89.5 | 89.3 | 89.6 | 90.3 | 90.3 | 88.9 | 89.6 | 89.9 | 90.6 | 90.2 | 91.0 | | |
| 14 | 94.0 | 92.4 | 91.2 | 92.4 | 94.7 | 93.2 | 93.4 | 92.8 | 92.8 | | | | |
| 15 | 83.8 | 82.3 | 81.8 | 83.7 | 83.9 | 83.1 | 81.8 | 83.1 | 84.0 | 83.7 | 83.5 | | |
| 16 | 89.0 | 89.7 | 89.3 | 89.3 | 91.0 | 89.0 | 87.0 | 89.4 | 89.1 | 88.4 | | | |
| 17 | 85.9 | 85.6 | 85.6 | | | | | | | | | | |
| 18 | 86.6 | 85.5 | 85.2 | 86.1 | 86.1 | | 83.0 | 85.1 | 86.1 | 86.5 | 85.4 | | |
| 19 | 86.3 | 87.9 | 86.0 | 85.8 | 85.6 | 86.7 | 86.2 | 85.9 | 86.4 | 86.2 | 85.8 | | |
| 20 | 101.7 | 101.1 | 101.2 | 99.0 | 102.1 | 102.4 | 101.9 | 101.6 | 101.0 | 101.1 | 100.5 | 99.7 | |
| 21 | 90.0 | 91.4 | 90.7 | 90.8 | 90.8 | 91.7 | 92.7 | 92.1 | 90.0 | 90.7 | 92.4 | 91.4 | |
| Summary: | MCV, fL | | | | | | | | | | | | |
| Average | 89.1 | 88.8 | 88.6 | 89.0 | 89.1 | 89.2 | 89.2 | 89.1 | 89.2 | 88.7 | 89.0 | 89.6 | 82.7 |
| Std Dev | 04.0 | 04.0 | 04.1 | 03.6 | 04.6 | 04.5 | 04.5 | 04.1 | 04.2 | 04.0 | 04.6 | 07.1 | 02.3 |
| Max | 101.7 | 101.1 | 101.2 | 99.0 | 102.1 | 102.4 | 101.9 | 101.6 | 101.0 | 101.1 | 100.5 | 99.7 | 84.0 |
| Min | 83.8 | 82.3 | 81.8 | 83.7 | 83.5 | 83.1 | 81.8 | 83.1 | 84.0 | 83.7 | 83.5 | 80.4 | 80.0 |

Figure 15: SD & Range Charts for MCV, fL



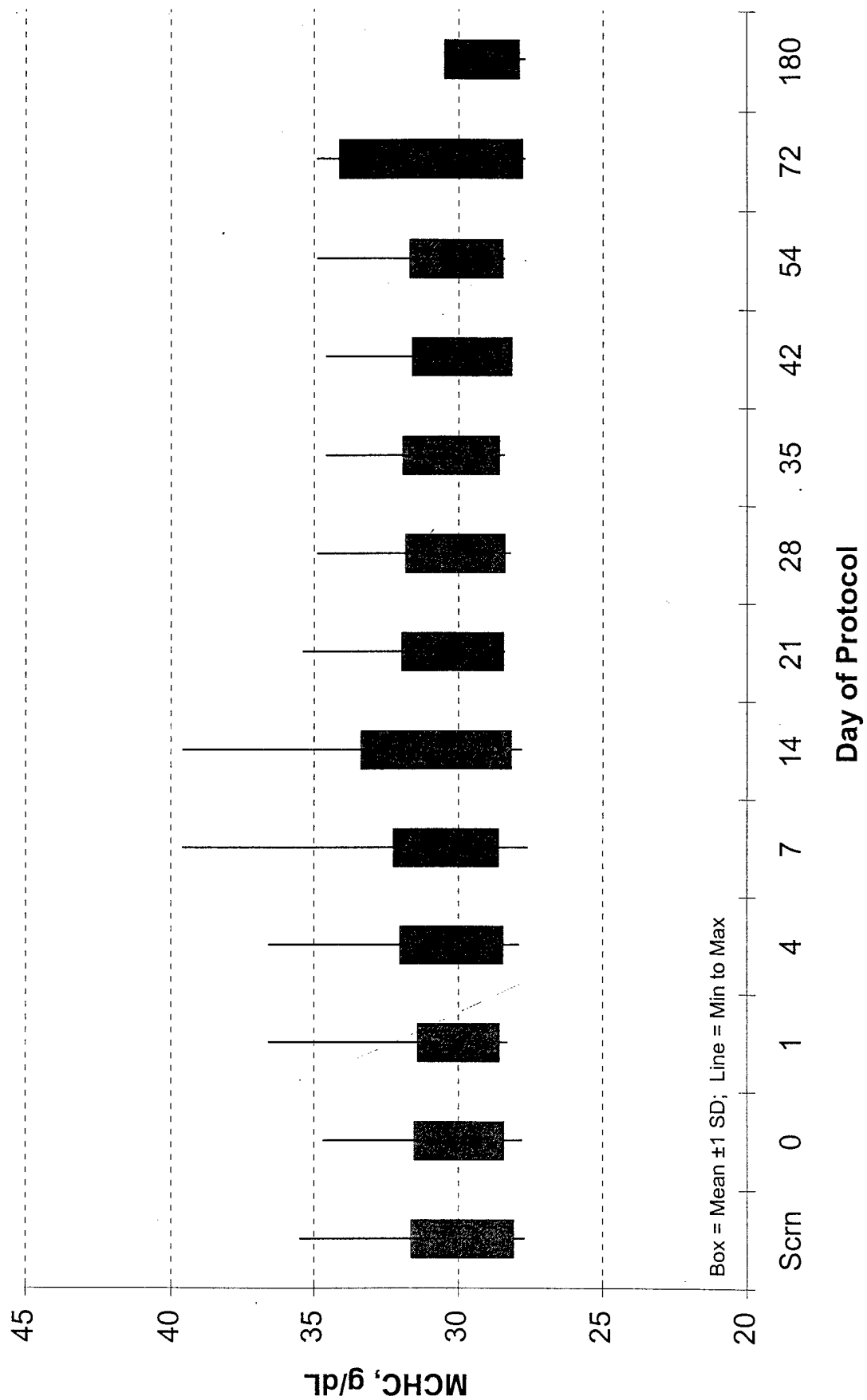
g/dL

Table 8f
MCHC

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | 29.9 | 31.5 | 30.0 | 30.1 | 30.2 | 30.1 | 30.1 | 29.8 | 30.3 | 30.1 | 29.6 | 29.0 | 30.1 |
| 02 | 30.6 | 31.5 | 30.1 | 30.8 | 30.8 | 30.3 | 30.4 | 30.6 | 30.1 | 29.8 | | | |
| 03 | 29.6 | 29.1 | 29.6 | 29.9 | 29.4 | 29.6 | 28.9 | 29.5 | 28.8 | 28.7 | 28.9 | 27.7 | 27.7 |
| 04 | 28.2 | 31.0 | 31.0 | 30.6 | 30.6 | 30.8 | 30.7 | 30.2 | 30.2 | | | | |
| 05 | 28.9 | 28.9 | 29.0 | 28.9 | 28.5 | 28.9 | 28.6 | 28.3 | | | | | |
| 06 | 29.3 | 29.7 | 29.5 | 29.4 | 29.4 | 29.7 | 30.1 | 30.0 | 30.6 | 29.4 | 28.9 | 29.4 | 29.8 |
| 07 | 29.8 | 30.1 | 29.7 | 29.8 | 33.4 | 30.8 | 30.8 | 28.3 | | 28.4 | 28.4 | | |
| 08 | 27.9 | 27.8 | 28.3 | 27.9 | 28.0 | | | | | | | | |
| 09 | 29.2 | 29.3 | 29.6 | 29.3 | 33.2 | 29.9 | 28.8 | 28.6 | 28.8 | 29.0 | 29.8 | | |
| 10 | 29.8 | 29.5 | 29.2 | 29.4 | 31.3 | 29.9 | 28.7 | 28.2 | 28.6 | 28.5 | 29.5 | | |
| 11 | 28.8 | 29.6 | 29.9 | 30.0 | 29.1 | 28.6 | 28.5 | 29.0 | | 29.3 | | | |
| 12 | 31.2 | 31.2 | 31.3 | 30.8 | 31.3 | 31.5 | 31.8 | 32.7 | 32.5 | 32.5 | 32.3 | | |
| 13 | 29.8 | 30.2 | 30.5 | 31.0 | 30.8 | 39.6 | 31.5 | 31.5 | 31.1 | 31.2 | 30.4 | | |
| 14 | 32.7 | 31.1 | 31.5 | 31.8 | 31.7 | 32.4 | 31.8 | 31.5 | 31.2 | | | | |
| 15 | 27.7 | 28.0 | 28.7 | 28.9 | 27.6 | 29.4 | 28.8 | 29.9 | 28.8 | 28.5 | 29.0 | | |
| 16 | 29.9 | 29.0 | 28.9 | 30.1 | 29.6 | 29.9 | 29.6 | 29.9 | 29.3 | 29.0 | | | |
| 17 | 28.9 | 28.4 | 28.9 | | | | | | | | | | |
| 18 | 28.9 | 28.5 | 28.6 | 28.5 | 28.5 | 27.8 | 28.4 | 28.3 | 28.4 | 28.3 | | | |
| 19 | 28.6 | 29.0 | 29.5 | 29.5 | 29.4 | 29.5 | 28.9 | 29.4 | 29.1 | 29.6 | 29.1 | | |
| 20 | 35.5 | 34.4 | 34.7 | 36.6 | 34.4 | 34.7 | 35.4 | 34.9 | 34.6 | 34.6 | 33.9 | 33.8 | |
| 21 | 31.9 | 31.6 | 31.4 | 31.5 | 31.4 | 31.3 | 32.0 | 31.6 | 31.7 | 31.2 | 31.1 | 34.9 | |
| Summary: | MCHC, g/dL | | | | | | | | | | | | |
| Average | 29.9 | 30.0 | 30.0 | 30.2 | 30.4 | 30.8 | 30.2 | 30.1 | 30.3 | 29.9 | 30.1 | 31.0 | 29.2 |
| Std Dev | 01.8 | 01.6 | 01.4 | 01.8 | 01.8 | 02.6 | 01.8 | 01.7 | 01.7 | 01.7 | 01.6 | 03.2 | 01.3 |
| Max | 35.5 | 34.7 | 36.6 | 36.6 | 39.6 | 39.6 | 35.4 | 34.9 | 34.6 | 34.6 | 34.9 | 34.9 | 30.1 |
| Min | 27.7 | 27.8 | 28.3 | 27.9 | 27.6 | 27.8 | 28.4 | 28.2 | 28.4 | 28.3 | 28.4 | 27.7 | 27.7 |

Figure 16: SD & Range Charts for MCHC, g/dL



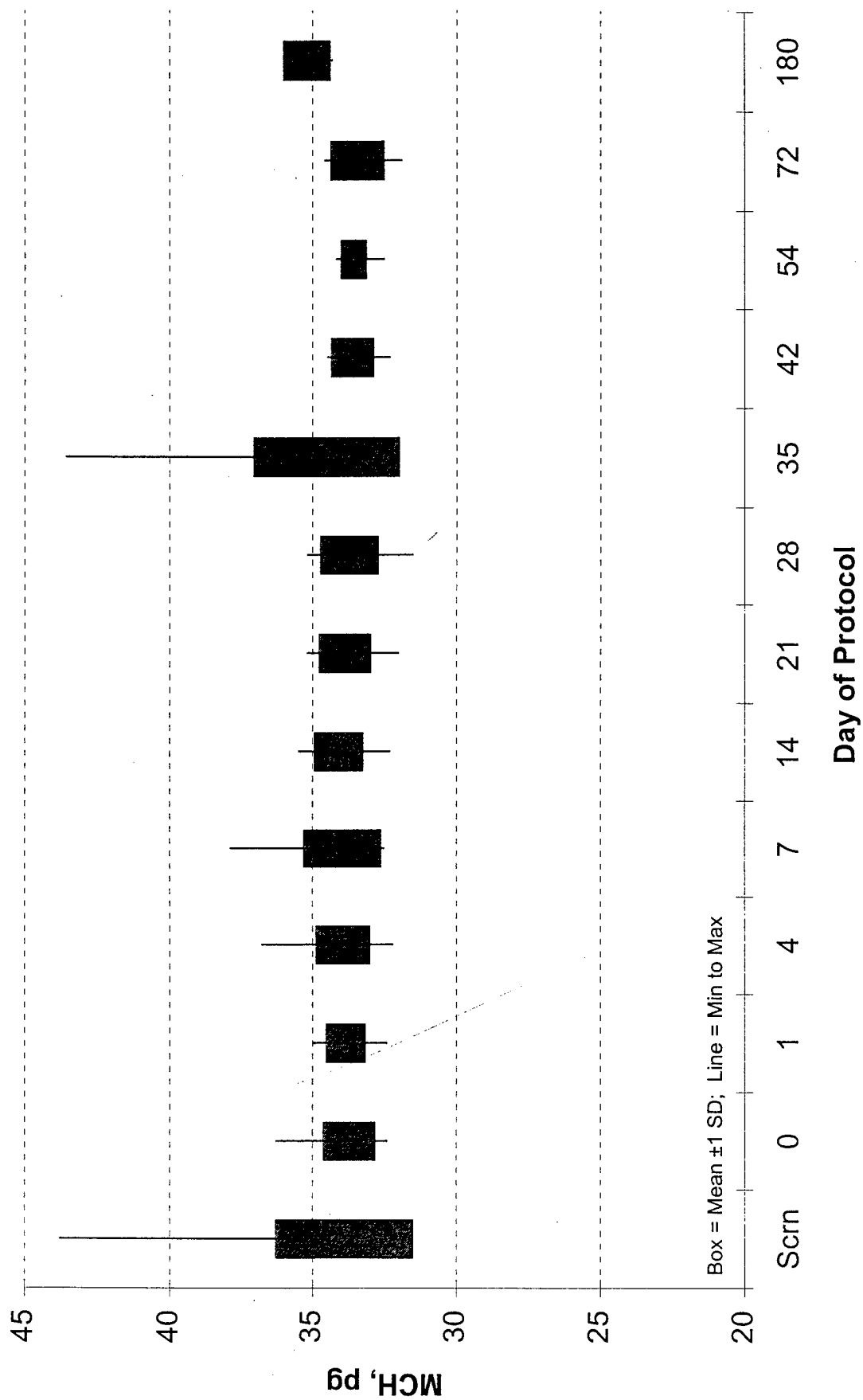
Blank = Not Obtained

Table 8g
MCH

Units: Picograms

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|---------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | 34.1 | 36.3 | 34.2 | 34.1 | 34.7 | 34.6 | 34.1 | 34.0 | 43.6 | 34.1 | 33.6 | 33.2 | 35.9 |
| 02 | 33.7 | 35.3 | 33.6 | 34.1 | 34.2 | 33.6 | 33.7 | 34.7 | 34.3 | 33.5 | | | |
| 03 | 33.7 | 33.2 | 34.1 | 34.3 | 33.2 | 34.4 | 33.3 | 34.3 | 33.6 | 33.8 | 33.6 | 33.1 | 34.3 |
| 04 | 31.5 | 34.4 | 34.2 | 34.1 | 33.6 | 34.5 | 34.2 | 33.3 | 33.6 | | | | |
| 05 | 33.2 | 33.3 | 33.3 | 33.2 | 33.3 | 33.9 | 32.8 | 32.7 | | | | | |
| 06 | 33.8 | 34.6 | 34.0 | 34.3 | 34.2 | 34.7 | 34.8 | 34.5 | 35.3 | 34.0 | 33.3 | 34.0 | 35.4 |
| 07 | 33.3 | 33.3 | 32.7 | 33.1 | 37.1 | 34.8 | 34.8 | 31.5 | | 32.5 | 32.5 | | |
| 08 | 32.5 | 32.9 | 33.4 | 32.8 | 33.3 | | | | | | | | |
| 09 | 33.2 | 33.5 | 34.1 | 33.2 | 37.9 | 34.4 | 32.7 | 32.6 | 33.0 | 33.0 | 33.6 | | |
| 10 | 33.7 | 33.5 | 33.2 | 33.5 | 33.4 | 34.1 | 32.7 | 32.3 | 32.9 | 32.9 | 34.0 | | |
| 11 | 32.9 | 33.8 | 34.7 | 34.3 | 33.3 | 32.3 | 32.0 | 32.7 | | 33.0 | | | |
| 12 | 32.8 | 32.6 | 32.7 | 32.2 | 32.6 | 33.1 | 33.1 | 34.5 | 35.0 | 34.3 | 34.2 | | |
| 13 | 33.3 | 33.8 | 34.0 | 34.3 | 34.1 | 35.5 | 35.2 | 35.1 | 34.4 | 34.5 | 33.4 | | |
| 14 | 43.8 | 33.6 | 34.5 | 34.4 | 33.5 | 34.7 | 34.0 | 33.9 | 33.6 | | | | |
| 15 | 33.1 | 33.9 | 35.0 | 34.5 | 32.9 | 35.3 | 35.1 | 35.2 | 34.3 | 34.1 | 34.1 | 34.6 | |
| 16 | 33.1 | 32.4 | 32.4 | 33.7 | 32.5 | 33.6 | 34.1 | 33.4 | 32.8 | 32.8 | | | |
| 17 | 33.5 | 33.2 | 33.7 | | | | | | | | | | |
| 18 | 33.3 | 33.2 | 33.6 | 33.0 | 33.1 | 32.3 | 34.3 | 33.2 | 33.0 | 32.3 | 33.1 | | |
| 19 | 33.1 | 32.9 | 34.4 | 34.3 | 34.3 | 34.0 | 33.6 | 34.2 | 33.7 | 34.4 | 33.9 | | |
| 20 | 34.9 | 34.0 | 34.3 | 36.8 | 33.6 | 33.8 | 34.7 | 34.4 | 34.2 | 34.2 | 33.5 | 33.9 | |
| 21 | 35.4 | 34.5 | 34.5 | 34.6 | 34.5 | 34.1 | 34.5 | 34.3 | 35.2 | 34.4 | 33.7 | 31.9 | |
| Summary: | MCH, pg | | | | | | | | | | | | |
| Average | 33.9 | 33.7 | 33.8 | 33.9 | 34.0 | 34.1 | 33.9 | 33.7 | 34.5 | 33.6 | 33.6 | 33.5 | 35.2 |
| Std Dev | 02.4 | 00.9 | 00.7 | 00.9 | 01.4 | 00.9 | 00.9 | 01.0 | 02.5 | 00.7 | 00.5 | 00.9 | 00.8 |
| Max | 43.8 | 36.3 | 35.0 | 36.8 | 37.9 | 35.5 | 35.2 | 35.2 | 43.6 | 34.5 | 34.2 | 34.6 | 35.9 |
| Min | 31.5 | 32.4 | 32.4 | 32.2 | 32.5 | 32.3 | 32.0 | 31.5 | 32.8 | 32.3 | 32.5 | 31.9 | 34.3 |

Figure 17: SD & Range Charts for MCH, pg



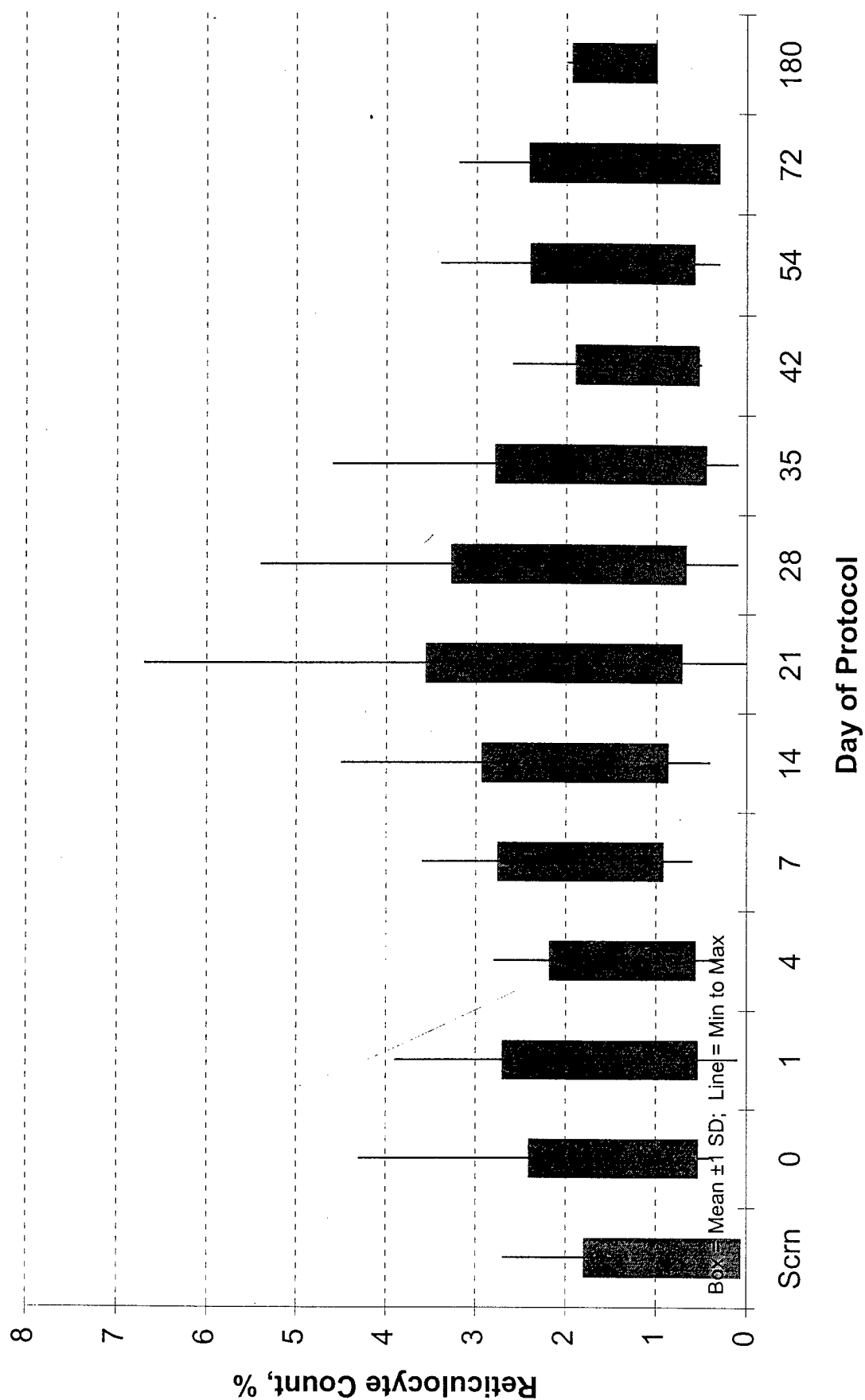
Units: %

Table 8h
Reticulocyte Count

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | | 2.0 | 0.7 | 2.5 | 1.8 | 1.5 | 1.5 | 1.5 | 2.0 | 1.5 | 1.9 | 1.0 | 1.1 |
| 02 | | 1.5 | 0.1 | 1.8 | 1.9 | 1.4 | 2.0 | 0.4 | 1.9 | 0.5 | | | |
| 03 | | 1.0 | 1.5 | 0.7 | 3.5 | 1.2 | 2.0 | 0.1 | 2.0 | 1.4 | 1.6 | 1.2 | 1.3 |
| 04 | 0.6 | 1.2 | 2.5 | 2.8 | 1.9 | 2.0 | 3.0 | 4.4 | 1.0 | | | | |
| 05 | 1.2 | 2.3 | 2.0 | 2.5 | 2.4 | 1.5 | 1.5 | 2.8 | | | | | |
| 06 | | 0.4 | 1.0 | 0.5 | | 3.6 | 1.6 | 1.5 | 1.0 | 1.0 | 0.8 | 0.9 | 2.0 |
| 07 | 1.0 | 0.5 | 0.2 | 1.1 | 1.0 | 2.4 | 3.8 | 1.3 | | 1.4 | 0.8 | | |
| 08 | 0.6 | 1.0 | 1.6 | 0.4 | 1.5 | | | | | | | | |
| 09 | 0.1 | 1.3 | 1.2 | 1.2 | 1.0 | 2.0 | 2.5 | 1.0 | 2.4 | 0.5 | 0.3 | | |
| 10 | | 2.0 | 0.1 | 0.3 | 1.0 | 1.7 | 2.0 | 1.1 | 0.1 | 0.6 | 1.2 | | |
| 11 | 2.7 | 4.3 | 2.1 | 0.9 | 3.0 | 4.5 | 6.7 | 5.4 | | 1.0 | | | |
| 12 | | 2.5 | 2.8 | 2.0 | 1.3 | 1.1 | 0.0 | 2.0 | 4.6 | 1.2 | | | |
| 13 | | | 3.3 | | 1.4 | 1.8 | 1.5 | 1.8 | 2.0 | 1.1 | 1.3 | | |
| 14 | | | 3.9 | 2.3 | 2.4 | 1.7 | 2.4 | 2.2 | 0.3 | | | | |
| 15 | | | 2.7 | 2.0 | 3.6 | 1.7 | 1.6 | 2.6 | 1.5 | 2.6 | 2.8 | | |
| 16 | | | 2.1 | 1.0 | 0.8 | 0.8 | 1.3 | 2.7 | 0.9 | 0.5 | | | |
| 17 | | 1.0 | 1.0 | | | | | | | | | | |
| 18 | | 1.2 | 1.3 | 0.6 | 0.6 | 0.8 | 0.9 | 1.5 | 1.5 | 2.4 | 0.9 | | |
| 19 | | 0.9 | 0.3 | 0.7 | 1.0 | 0.4 | 1.8 | 1.0 | 0.3 | | | | |
| 20 | | 0.9 | | | 1.8 | 2.5 | 3.5 | 3.0 | 1.0 | 2.0 | 1.4 | 3.2 | |
| 21 | 0.3 | 1.0 | 2.0 | 1.4 | 3.0 | 3.5 | 1.0 | 1.2 | 3.4 | 0.5 | 3.4 | 0.5 | |
| Summary: | | | | | | | | | | | | | |
| Average | 0.9 | 1.5 | 1.6 | 1.4 | 1.8 | 1.9 | 2.1 | 2.0 | 1.6 | 1.2 | 1.5 | 1.4 | 1.5 |
| Std Dev | 0.9 | 0.9 | 1.1 | 0.8 | 0.9 | 1.0 | 1.4 | 1.3 | 1.2 | 0.7 | 0.9 | 1.1 | 0.5 |
| Max | 2.7 | 4.3 | 3.9 | 2.8 | 3.6 | 4.5 | 6.7 | 5.4 | 4.6 | 2.6 | 3.4 | 3.2 | 2.0 |
| Min | 0.1 | 0.4 | 0.1 | 0.3 | 0.6 | 0.4 | 0.0 | 0.1 | 0.1 | 0.5 | 0.3 | 0.5 | 1.1 |

Figure 18: SD & Range Charts for Reticulocyte Count, %



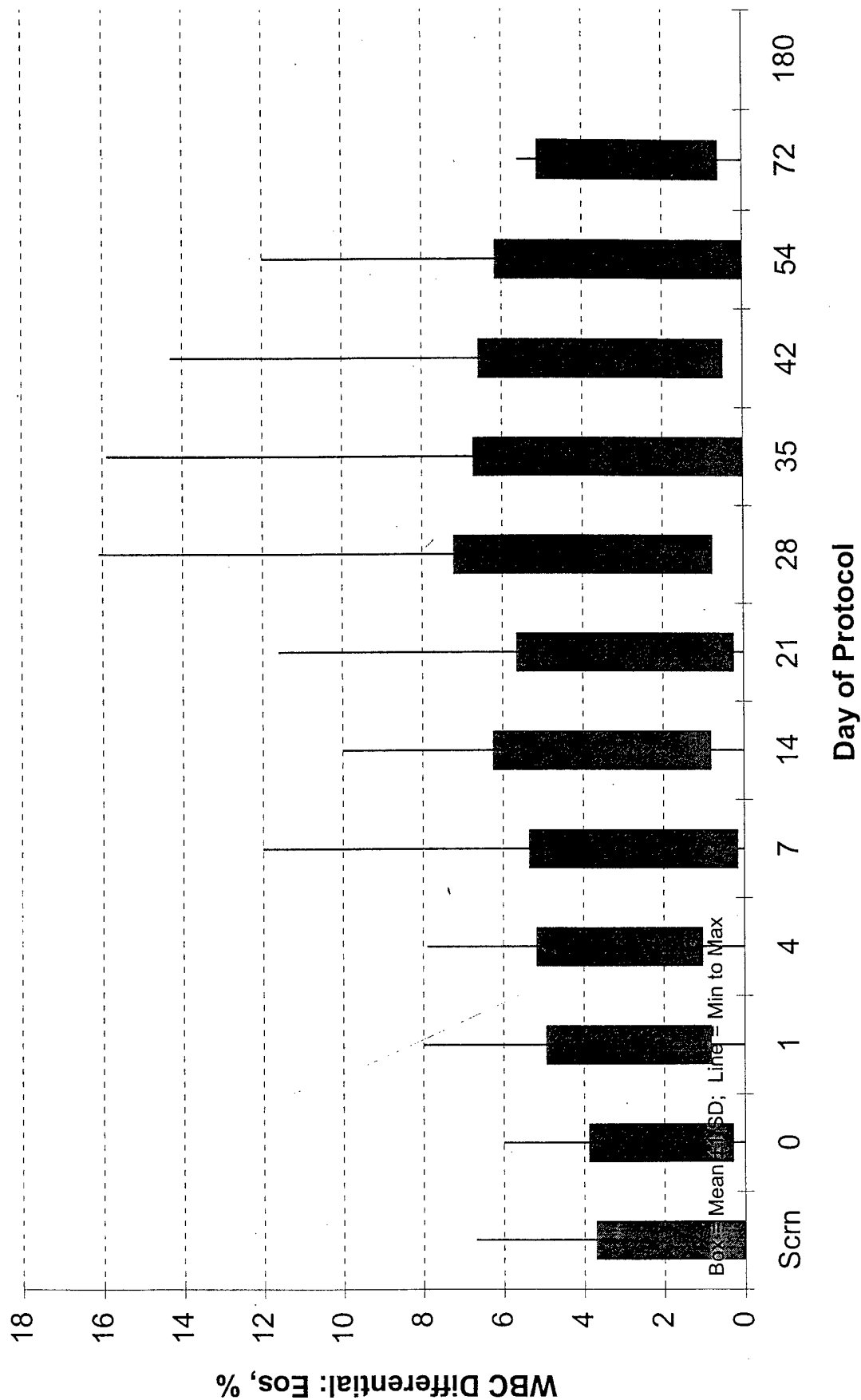
Units: %

Table 8i
WBC Differential: Eosinophils

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|---------|--------------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 0.0 | 0.0 | 5.1 | 5.1 | 4.6 | 5.4 | 6.2 | 5.8 | 5.6 | 3.3 | 3.9 | 5.6 | 0.0 |
| 02 | 0.0 | 0.0 | 3.0 | 4.8 | 4.9 | 5.1 | 5.5 | 6.2 | 0.3 | 1.9 | | | |
| 03 | 1.2 | 1.3 | 1.2 | 2.1 | 1.3 | 2.2 | 2.3 | 2.5 | 1.7 | 1.4 | 3.5 | 0.0 | 0.0 |
| 04 | | 1.1 | 1.3 | 1.0 | 1.7 | 0.0 | 0.9 | 0.8 | 0.0 | | | | |
| 05 | 4.7 | 6.0 | 5.7 | 4.0 | 0.0 | 0.0 | 3.8 | 3.4 | | | | | |
| 06 | 0.0 | 0.7 | 1.9 | 0.0 | 1.9 | 2.3 | 1.9 | 2.7 | 2.1 | 2.2 | 1.5 | 2.0 | 0.0 |
| 07 | 0.0 | 2.8 | 3.6 | 5.6 | 3.8 | 6.0 | 0.0 | 3.9 | | 3.5 | 0.0 | | |
| 08 | 4.0 | 5.4 | 5.9 | 6.0 | 0.0 | | | | | | | | |
| 09 | 1.2 | 1.0 | 2.5 | 2.3 | 1.3 | 2.0 | 1.7 | 1.5 | 0.8 | 1.7 | 1.0 | | |
| 10 | 2.0 | 2.5 | 2.3 | 1.2 | 2.0 | 1.8 | 1.8 | 2.9 | 1.7 | 2.1 | 1.8 | | |
| 11 | 2.4 | 0.9 | 0.0 | 4.0 | 0.0 | 3.3 | 3.1 | 3.8 | | 4.7 | | | |
| 12 | 0.9 | 0.8 | 1.6 | 2.4 | 2.0 | 2.2 | 1.6 | 1.8 | 0.0 | 1.7 | 1.7 | | |
| 13 | 2.5 | 1.4 | 4.2 | 3.7 | 3.1 | 3.8 | 3.5 | 3.5 | 4.3 | 5.1 | 4.7 | 4.7 | |
| 14 | 0.0 | 1.4 | 2.0 | 2.0 | 1.2 | 1.7 | 2.0 | 4.1 | 2.0 | | | | |
| 15 | 6.7 | 5.2 | 8.0 | 7.9 | 12.0 | 9.6 | 11.6 | 16.1 | 15.9 | 14.3 | 12.0 | | 0.0 |
| 16 | 0.0 | 2.2 | 3.2 | 3.3 | 3.2 | 3.7 | 0.0 | 4.9 | 3.5 | 3.0 | | | |
| 17 | | | | | | | | | | | | | |
| 18 | 2.8 | 3.6 | 1.0 | 1.0 | 3.7 | 3.4 | 0.0 | 3.2 | 3.1 | 3.1 | 2.4 | | |
| 19 | 2.7 | 2.8 | 0.0 | 3.0 | 2.6 | 2.0 | 3.3 | 3.4 | 3.3 | 2.7 | 3.0 | | |
| 20 | 2.2 | 0.0 | 3.0 | 0.0 | 2.7 | 10.0 | 4.0 | 2.3 | 2.0 | 2.5 | 1.1 | 2.0 | |
| 21 | 2.1 | 2.6 | 2.3 | 2.7 | 3.1 | 2.6 | 2.8 | 3.0 | 0.0 | 3.4 | | | |
| Summary | WBC Differential: Eos, % | | | | | | | | | | | | |
| Average | 1.9 | 2.1 | 2.9 | 3.1 | 2.8 | 3.5 | 2.9 | 4.0 | 2.9 | 3.5 | 3.1 | 2.9 | 0.0 |
| Std Dev | 1.8 | 1.8 | 2.1 | 2.1 | 2.6 | 2.7 | 2.7 | 3.2 | 3.8 | 3.1 | 3.1 | 2.3 | 0.0 |
| Max | 6.7 | 6.0 | 8.0 | 7.9 | 12.0 | 10.0 | 11.6 | 16.1 | 15.9 | 14.3 | 12.0 | 5.6 | 0.0 |
| Min | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.8 | 0.0 | 1.4 | 0.0 | 0.0 | 0.0 |

Figure 19: SD & Range Charts for WBC Differential: Eos, %



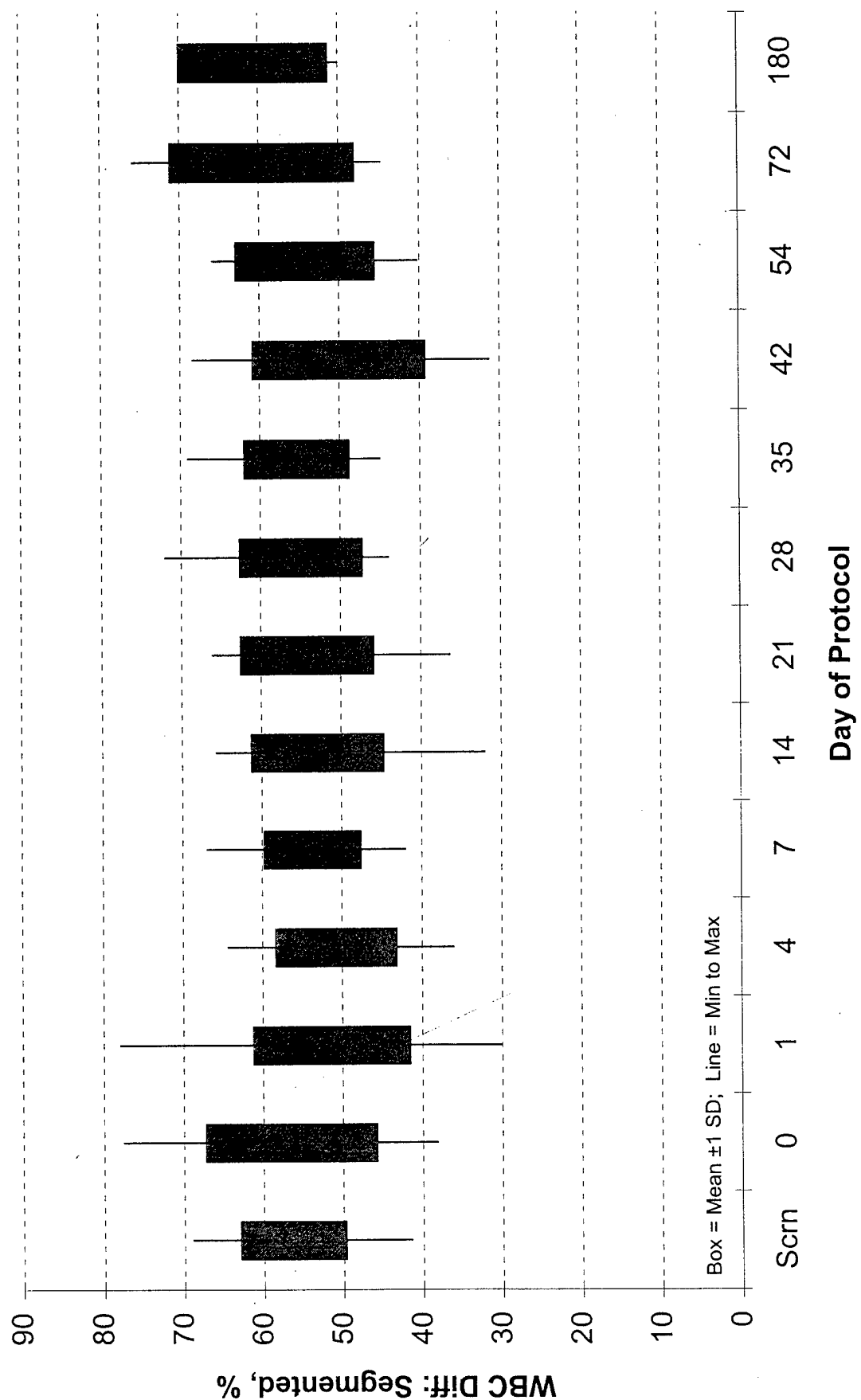
Units: %

Table 8j
WBC Differential: Segmented

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 66.0 | 68.0 | 51.4 | 51.7 | 55.9 | 57.6 | 56.3 | 60.0 | 57.5 | 65.1 | 52.8 | 52.2 | 68.0 |
| 02 | 50.0 | 52.0 | 46.0 | 49.2 | 50.3 | 45.7 | 44.0 | 50.9 | 56.5 | 37.5 | | | |
| 03 | 54.2 | 53.2 | 51.0 | 43.0 | 63.8 | 48.5 | 47.7 | 44.6 | 52.2 | 47.6 | 57.7 | 76.0 | 50.0 |
| 04 | | 64.9 | 57.7 | 60.3 | 52.5 | 59.0 | 65.1 | 72.1 | 61.0 | | | | |
| 05 | 50.1 | 51.4 | 45.7 | 41.0 | 51.0 | 59.0 | 51.0 | 51.3 | 57.4 | | | | |
| 06 | 58.0 | 64.8 | 54.1 | 58.0 | 58.1 | 60.8 | 66.2 | 55.7 | 59.1 | 60.9 | 58.2 | 70.6 | 64.0 |
| 07 | 52.0 | 46.5 | 48.7 | 46.4 | 54.3 | 53.2 | 58.0 | 60.3 | | 53.6 | 63.0 | | |
| 08 | 48.0 | 38.1 | 35.1 | 36.0 | 42.0 | | | | | | | | |
| 09 | 61.1 | 67.2 | 61.9 | 64.4 | 67.0 | 53.0 | 65.7 | 66.8 | 69.2 | 68.5 | 65.2 | | |
| 10 | 51.6 | 48.3 | 49.5 | 57.7 | 49.0 | 58.0 | 63.5 | 58.8 | 54.2 | 49.7 | 45.6 | | |
| 11 | 63.3 | 77.6 | 78.0 | 42.4 | 52.0 | 52.2 | 59.7 | 58.8 | | 54.7 | | | |
| 12 | 60.2 | 53.0 | 56.5 | 49.2 | 51.6 | 55.8 | 52.1 | 55.0 | 56.0 | 53.9 | 55.7 | | |
| 13 | 54.4 | 53.9 | 42.1 | 48.2 | 54.4 | 46.0 | 43.9 | 43.9 | 46.7 | 43.6 | 40.2 | 57.9 | |
| 14 | 69.0 | 56.5 | 56.6 | 56.0 | 61.5 | 59.1 | 55.9 | 62.9 | 65.5 | | | | |
| 15 | 41.4 | 40.0 | 47.0 | 41.8 | 47.0 | 38.5 | 36.3 | 43.9 | 44.9 | 37.0 | 43.0 | | |
| 16 | 60.0 | 65.0 | 57.2 | 54.1 | 56.3 | 57.6 | 62.0 | 50.3 | 53.8 | 53.2 | | | |
| 17 | 58.9 | 72.0 | 54.0 | | | | | | | | | | |
| 18 | 61.4 | 48.8 | 46.0 | 53.0 | 47.2 | 46.4 | 51.0 | 51.3 | 45.2 | 31.2 | 42.8 | | |
| 19 | 53.3 | 55.3 | 50.0 | 51.5 | 48.3 | 65.8 | 45.9 | 49.6 | 49.9 | 58.9 | 56.1 | | |
| 20 | 52.6 | 43.0 | 30.0 | 49.0 | 51.6 | 32.0 | 50.0 | 48.5 | 53.1 | 35.3 | 66.0 | 44.7 | |
| 21 | 60.4 | 66.1 | 60.1 | 62.0 | 59.9 | 58.9 | 56.3 | 59.3 | 60.0 | 50.9 | 59.4 | 56.5 | |
| Summary: | | | | | | | | | | | | | |
| Average | 56.3 | 56.5 | 51.4 | 50.7 | 53.7 | 53.0 | 54.2 | 54.9 | 55.4 | 50.1 | 54.3 | 59.7 | 60.7 |
| Std Dev | 06.7 | 10.8 | 09.9 | 07.6 | 06.1 | 08.4 | 08.4 | 07.8 | 06.7 | 10.9 | 08.8 | 11.7 | 09.5 |
| Max | 69.0 | 77.6 | 78.0 | 64.4 | 67.0 | 65.8 | 66.2 | 72.1 | 69.2 | 68.5 | 66.0 | 76.0 | 68.0 |
| Min | 41.4 | 38.1 | 30.0 | 36.0 | 42.0 | 32.0 | 36.3 | 43.9 | 44.9 | 31.2 | 40.2 | 44.7 | 50.0 |

Figure 20: SD & Range Charts for WBC Diff: Segmented, %



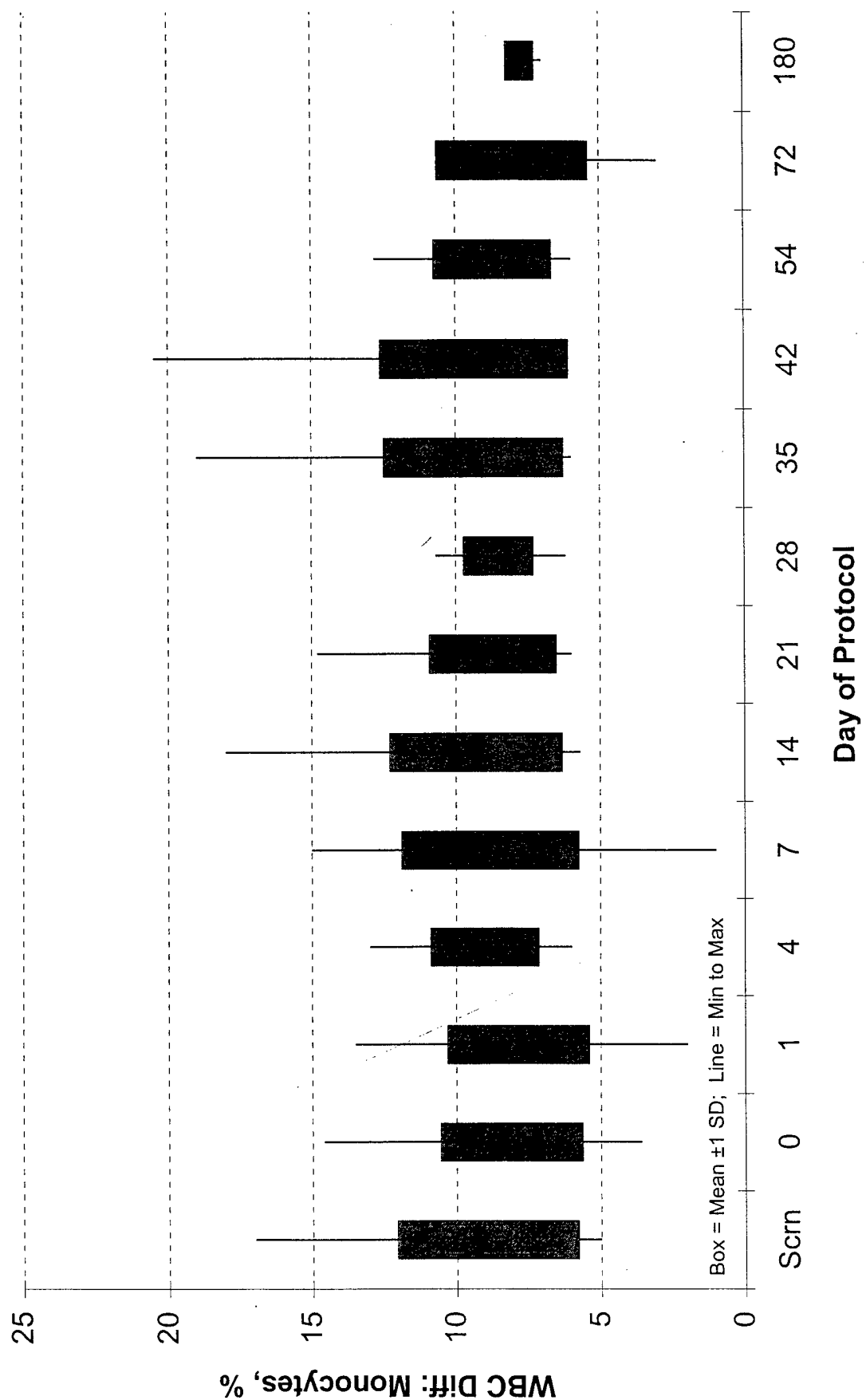
Units: %

Table 8k
WBC Differential: Monocytes

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 7.0 | 6.0 | 8.0 | 9.7 | 7.6 | 7.4 | 8.7 | 7.8 | 8.6 | 6.2 | 9.1 | 9.7 | 8.0 |
| 02 | 17.0 | 11.0 | 2.0 | 12.8 | 10.9 | 13.2 | 14.8 | 8.9 | 19.0 | 20.5 | | | |
| 03 | 6.5 | 7.8 | 7.0 | 6.5 | 6.2 | 5.7 | 6.5 | 6.2 | 6.5 | 7.8 | 6.0 | 3.0 | 8.0 |
| 04 | | 3.6 | 6.1 | 7.5 | 7.5 | 6.0 | 7.4 | 8.0 | 6.0 | | | | |
| 05 | 6.8 | 8.3 | 8.9 | 9.0 | 12.0 | 7.0 | 10.0 | 8.1 | | | | | |
| 06 | 7.0 | 6.7 | 8.6 | 8.0 | 7.4 | 7.0 | 7.1 | 7.5 | 7.7 | 8.2 | 7.1 | 7.9 | 7.0 |
| 07 | 9.0 | 9.5 | 9.6 | 10.9 | 10.2 | 10.2 | 10.0 | 10.7 | | 10.5 | 7.0 | | |
| 08 | 17.0 | 14.6 | 13.5 | 13.0 | 15.0 | | | | | | | | |
| 09 | 10.5 | 9.5 | 9.6 | 8.9 | 8.0 | 11.0 | 8.1 | 9.4 | 10.1 | 8.0 | 8.6 | | |
| 10 | 5.0 | 8.3 | 7.8 | 10.5 | 1.0 | 8.1 | 8.2 | 8.9 | 8.9 | 8.5 | 12.8 | | |
| 11 | 7.5 | 8.4 | 6.0 | 9.3 | 6.0 | 8.6 | 6.6 | 6.8 | | 8.1 | | | |
| 12 | 7.6 | 6.3 | 8.3 | 7.1 | 8.4 | 7.1 | 8.2 | 8.2 | 8.0 | 8.3 | 7.6 | | |
| 13 | 9.2 | 9.4 | 10.0 | 8.1 | 11.8 | 10.5 | 9.9 | 9.9 | 11.1 | 10.3 | 12.6 | 8.1 | |
| 14 | 10.0 | 10.8 | 12.1 | 11.0 | 12.6 | 12.2 | 12.5 | 10.2 | 12.1 | | | | |
| 15 | 7.0 | 8.4 | 6.0 | 8.4 | 10.0 | 8.8 | 7.5 | 8.4 | 6.7 | 7.6 | 8.0 | | 8.0 |
| 16 | 6.0 | 5.7 | 7.4 | 7.4 | 6.9 | 8.4 | 6.0 | 7.8 | 7.4 | 7.3 | | | |
| 17 | 10.2 | 5.0 | 8.3 | | | | | | | | | | |
| 18 | 9.6 | 10.6 | 8.0 | 6.0 | 12.0 | 11.8 | 11.0 | 8.8 | 10.5 | 9.8 | 10.0 | | |
| 19 | 7.7 | 7.4 | 6.0 | 8.6 | 7.6 | 7.2 | 7.6 | 7.3 | 7.9 | 7.6 | 7.3 | | |
| 20 | 8.7 | 6.0 | 7.0 | 9.0 | 7.7 | 18.0 | 8.0 | 10.4 | 10.6 | 11.4 | 8.8 | 10.4 | |
| 21 | 9.1 | 6.8 | 4.8 | 8.6 | 7.6 | 8.7 | 7.6 | 8.6 | 9.0 | 9.6 | 8.4 | 9.0 | |
| Summary: | WBC Diff: Monocytes, % | | | | | | | | | | | | |
| Average | 8.9 | 8.1 | 7.9 | 9.0 | 8.8 | 9.3 | 8.7 | 8.5 | 9.4 | 9.4 | 8.7 | 8.0 | 7.8 |
| Std Dev | 3.1 | 2.5 | 2.5 | 1.9 | 3.1 | 3.0 | 2.2 | 1.2 | 3.1 | 3.3 | 2.0 | 2.6 | 0.5 |
| Max | 17.0 | 14.6 | 13.5 | 13.0 | 15.0 | 18.0 | 14.8 | 10.7 | 19.0 | 20.5 | 12.8 | 10.4 | 8.0 |
| Min | 5.0 | 3.6 | 2.0 | 6.0 | 1.0 | 5.7 | 6.0 | 6.2 | 6.0 | 6.2 | 6.0 | 3.0 | 7.0 |

Figure 21: SD & Range Charts for WBC Diff: Monocytes, %



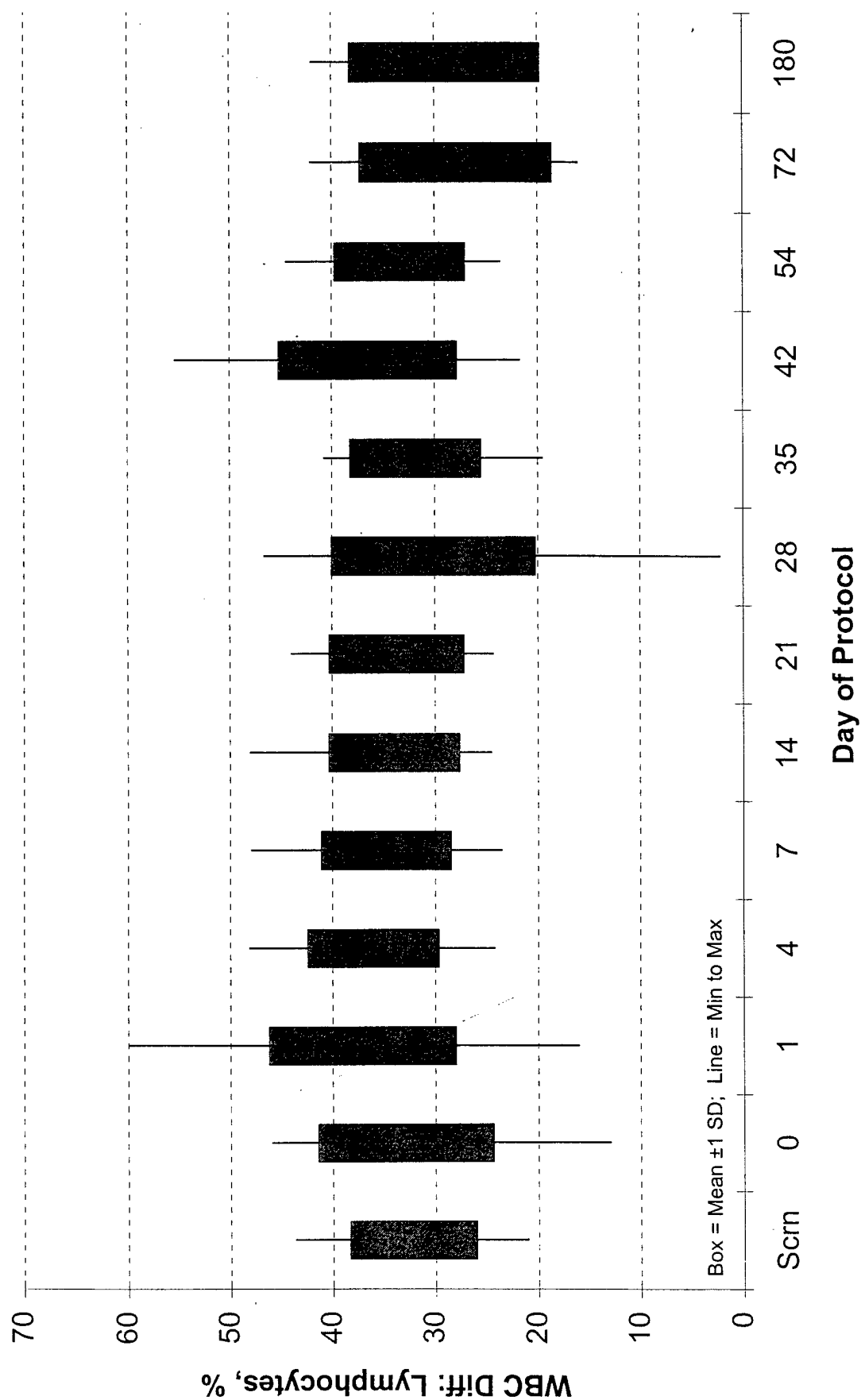
Units: %

Table 8L
WBC Differential: Lymphocytes

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|--------------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 27.0 | 26.0 | 35.5 | 33.0 | 39.5 | 29.1 | 28.3 | 26.2 | 28.2 | 25.4 | 34.1 | 31.6 | 24.0 |
| 02 | 33.0 | 37.0 | 48.0 | 31.9 | 33.5 | 35.2 | 35.0 | 34.0 | 23.8 | 39.6 | | | |
| 03 | 37.7 | 37.7 | 40.7 | 48.2 | 28.3 | 43.3 | 43.3 | 46.7 | 39.4 | 42.9 | 32.9 | 16.0 | 42.0 |
| 04 | | 30.2 | 34.1 | 30.9 | 38.8 | 35.0 | 26.2 | 18.5 | 33.0 | | | | |
| 05 | 38.4 | 34.1 | 39.4 | 45.0 | 37.0 | 34.0 | 34.9 | 31.0 | | | | | |
| 06 | 35.0 | 27.6 | 35.1 | 34.0 | 32.5 | 29.4 | 24.5 | 33.7 | 30.6 | 28.1 | 33.0 | 19.1 | 29.0 |
| 07 | 39.0 | 40.9 | 38.1 | 36.2 | 31.1 | 30.2 | 32.0 | 24.4 | | 32.3 | 28.0 | | |
| 08 | 31.0 | 41.7 | 45.0 | 34.0 | 43.0 | | | | | | | | |
| 09 | 27.2 | 22.2 | 26.0 | 24.2 | 23.5 | 27.0 | 24.3 | 21.2 | 19.5 | 21.7 | 24.9 | | |
| 10 | 38.5 | 40.9 | 39.6 | 30.2 | 48.0 | 32.0 | 26.2 | 28.7 | 32.1 | 38.7 | 39.2 | | |
| 11 | 26.3 | 12.9 | 16.0 | 44.0 | 42.0 | 35.5 | 30.3 | 2.2 | | 31.5 | | | |
| 12 | 30.9 | 39.6 | 33.2 | 39.8 | 37.0 | 34.9 | 37.7 | 34.9 | 36.0 | 35.9 | 34.5 | | |
| 13 | 33.6 | 35.2 | 43.6 | 39.1 | 30.6 | 39.6 | 42.6 | 42.6 | 37.8 | 40.9 | 42.5 | 29.2 | |
| 14 | 21.0 | 31.0 | 29.2 | 29.0 | 24.2 | 26.5 | 28.9 | 21.9 | 19.8 | | | | |
| 15 | 43.7 | 46.0 | 37.0 | 41.7 | 31.0 | 42.6 | 44.0 | 31.0 | 32.0 | 39.9 | 37.0 | | 21.0 |
| 16 | 34.0 | 26.7 | 32.0 | 35.2 | 31.5 | 30.0 | 31.0 | 35.7 | 34.4 | 35.7 | | | |
| 17 | 21.2 | 22.0 | 29.5 | | | | | | | | | | |
| 18 | 26.0 | 36.6 | 44.0 | 40.0 | 36.9 | 48.1 | 38.0 | 36.1 | 40.8 | 55.4 | 44.5 | | |
| 19 | 35.9 | 33.1 | 44.0 | 36.1 | 40.2 | 24.5 | 42.9 | 39.1 | 37.5 | 29.9 | 32.3 | | |
| 20 | 36.4 | 45.0 | 60.0 | 42.0 | 37.9 | 40.0 | 38.0 | 36.1 | 34.0 | 50.5 | 23.6 | 42.1 | |
| 21 | 27.8 | 24.0 | 29.1 | 26.2 | 28.8 | 28.7 | 32.7 | 28.6 | 31.0 | 35.8 | 27.6 | 29.5 | |
| Summary: | WBC Diff: Lymphocytes, % | | | | | | | | | | | | |
| Average | 32.2 | 32.9 | 37.1 | 36.0 | 34.8 | 34.0 | 33.7 | 30.1 | 31.9 | 36.5 | 33.4 | 27.9 | 29.0 |
| Std Dev | 6.2 | 8.6 | 9.2 | 6.4 | 6.4 | 6.4 | 6.6 | 9.9 | 6.4 | 8.7 | 6.4 | 9.4 | 9.3 |
| Max | 43.7 | 46.0 | 60.0 | 48.2 | 48.0 | 48.1 | 44.0 | 46.7 | 40.8 | 55.4 | 44.5 | 42.1 | 42.0 |
| Min | 21.0 | 12.9 | 16.0 | 24.2 | 23.5 | 24.5 | 24.3 | 2.2 | 19.5 | 21.7 | 23.6 | 16.0 | 21.0 |

Figure 22: SD & Range Charts for WBC Diff: Lymphocytes, %



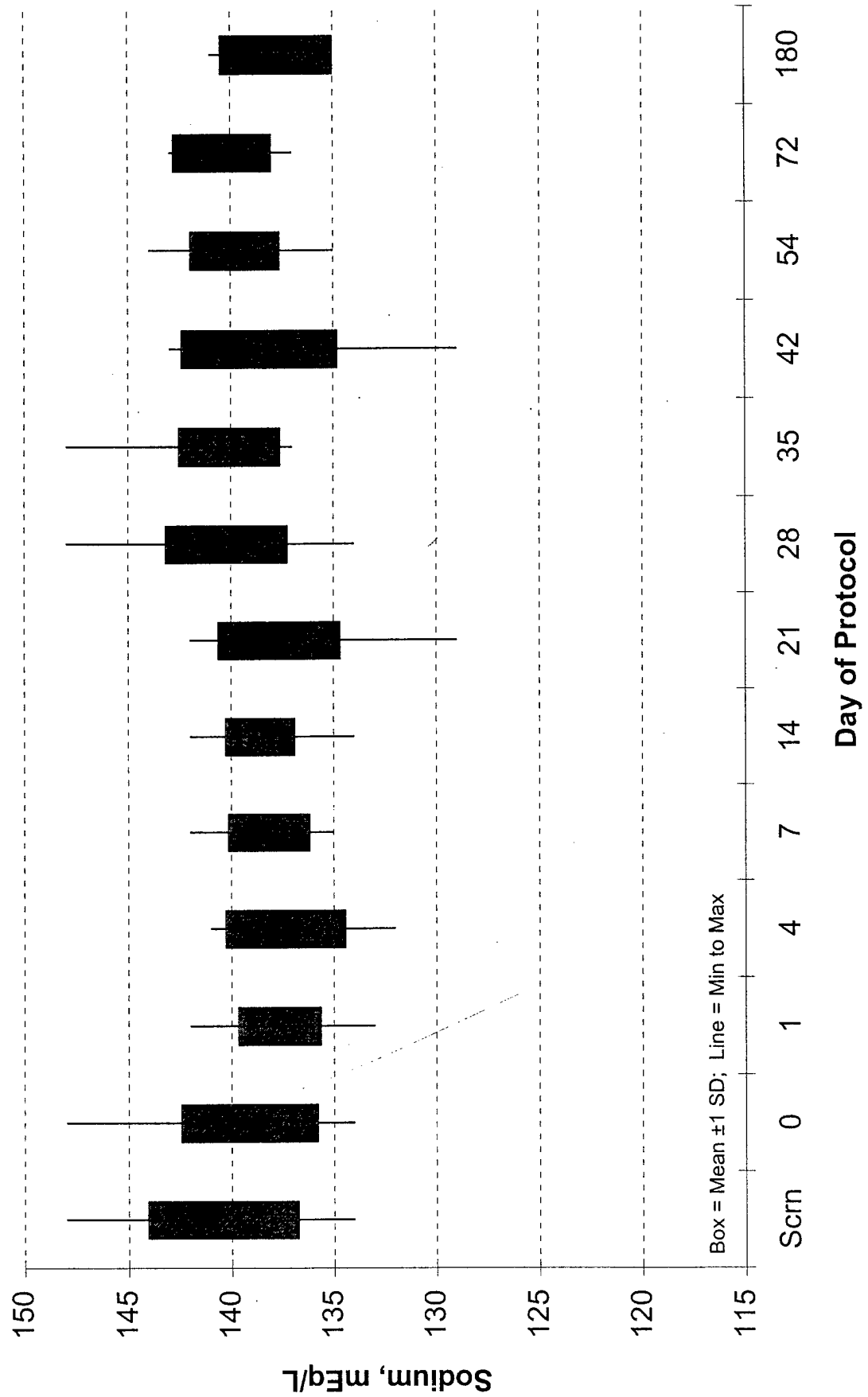
Units: mEq/L

Table 9a
Sodium

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|---------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 138 | 136 | 137 | 140 | 137 | 140 | 140 | 140 | 142 | 140 | 141 | 139 | 141 |
| 02 | 136 | 136 | 138 | 138 | 137 | 138 | 136 | 148 | 148 | 129 | | | |
| 03 | 140 | 140 | 141 | 136 | 136 | 134 | | 140 | 140 | 141 | 140 | 142 | 139 |
| 04 | 141 | 141 | 138 | 134 | 139 | 139 | | 141 | 138 | | | | |
| 05 | 142 | | 136 | 139 | 142 | 142 | 142 | 142 | | | | | |
| 06 | 142 | 142 | 137 | 141 | 138 | 139 | 141 | 140 | 140 | 138 | 140 | 137 | 135 |
| 07 | 136 | | 133 | 132 | 138 | 139 | 140 | 143 | 138 | 141 | 141 | | |
| 08 | 147 | 138 | 137 | 135 | 137 | | | | | | | | |
| 09 | 148 | 141 | 142 | 138 | 139 | 139 | 140 | 142 | 140 | 143 | 142 | | |
| 10 | 137 | 134 | 137 | 132 | 135 | 137 | 135 | 137 | 138 | 138 | 135 | | |
| 11 | 145 | 135 | 135 | 138 | 137 | 140 | 139 | 138 | | 138 | | | |
| 12 | 137 | 139 | | 140 | 141 | 141 | 136 | 140 | 138 | 140 | 141 | | |
| 13 | 140 | 148 | 139 | 141 | 142 | 139 | 138 | 134 | 140 | 139 | 141 | | |
| 14 | 141 | 138 | 136 | 137 | 137 | 137 | 136 | 140 | 140 | | | | |
| 15 | 140 | 139 | 139 | 141 | 141 | 138 | 139 | 140 | 139 | 142 | 139 | | 136 |
| 16 | 141 | 141 | 138 | 141 | 139 | 138 | 138 | 140 | 140 | 143 | 139 | | |
| 17 | | 140 | 139 | | | | | | | | | | |
| 18 | 134 | 135 | 137 | 134 | 137 | 137 | 136 | 141 | 141 | 133 | 138 | | |
| 19 | 141 | 142 | 137 | 138 | 136 | 138 | 129 | 141 | 137 | | 138 | | |
| 20 | 138 | 139 | 140 | 137 | 138 | 139 | 138 | 142 | 140 | 135 | 138 | 141 | |
| 21 | 144 | | 137 | 135 | 137 | 139 | 137 | 135 | 142 | 139 | 144 | 143 | |
| Summary: | Sodium, mEq/L | | | | | | | | | | | | |
| Average | 140 | 139 | 138 | 137 | 138 | 139 | 138 | 140 | 140 | 139 | 140 | 140 | 138 |
| Std Dev | 04 | 03 | 02 | 03 | 02 | 02 | 03 | 03 | 02 | 04 | 02 | 02 | 03 |
| Max | 148 | 148 | 142 | 141 | 142 | 142 | 142 | 148 | 148 | 143 | 144 | 143 | 141 |
| Min | 134 | 134 | 133 | 132 | 135 | 134 | 129 | 134 | 137 | 129 | 135 | 137 | 135 |

Figure 23: SD & Range Charts for Sodium, mEq/L



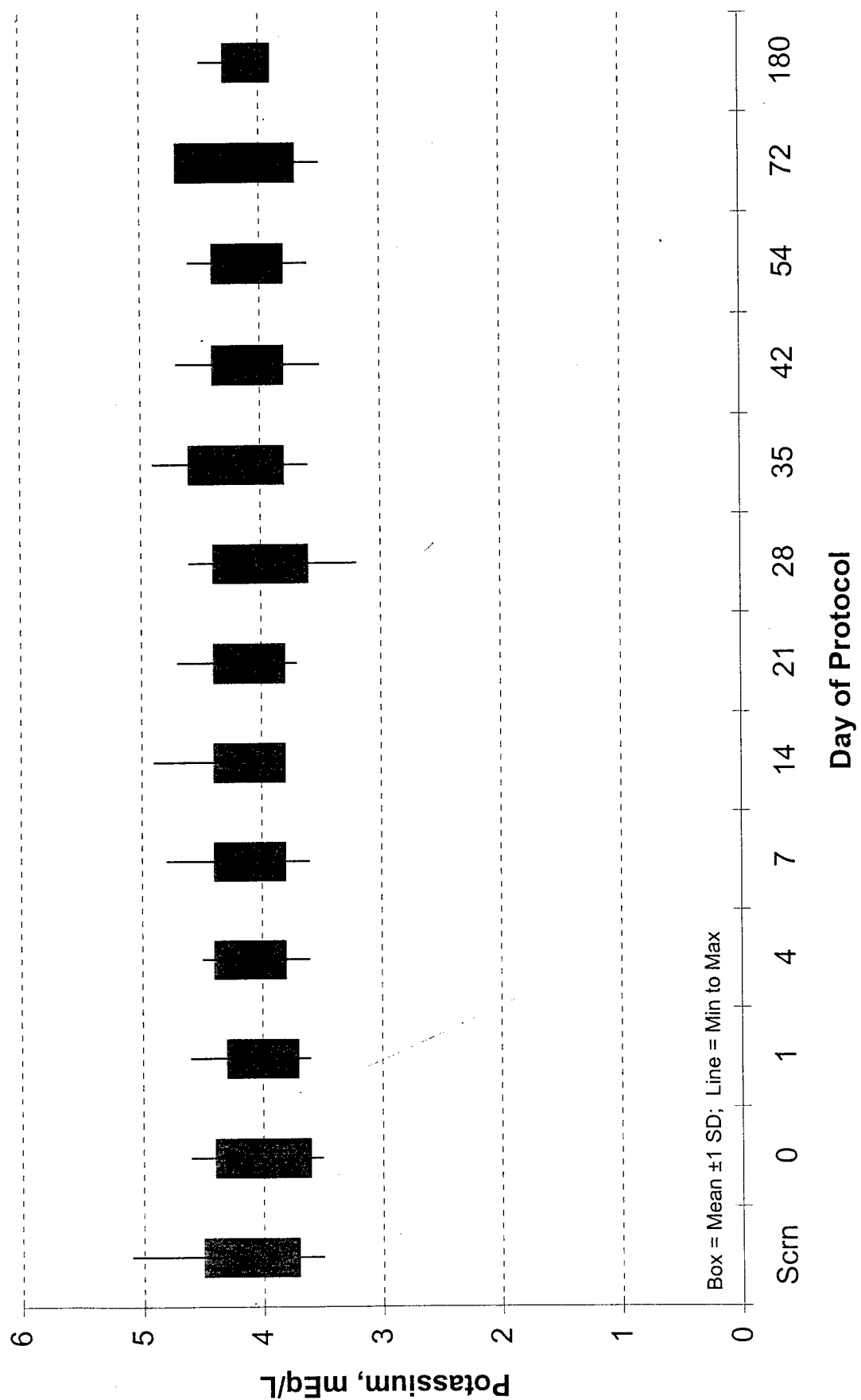
Units: mEq/L

Table 9b
Potassium

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | 3.9 | 3.5 | 3.9 | 3.7 | 3.6 | 3.8 | 3.7 | 3.3 | 3.7 | 3.8 | 3.6 | 3.7 | 4.0 |
| 02 | 4.1 | 4.1 | 4.4 | 4.2 | 3.9 | 4.0 | 4.1 | 3.9 | 3.6 | 4.5 | | | |
| 03 | 3.8 | 4.3 | 4.3 | 4.5 | 4.1 | 4.2 | 4.2 | 4.2 | 4.1 | 4.7 | 4.1 | 4.4 | 4.2 |
| 04 | 3.7 | 3.5 | 4.5 | 3.9 | 4.2 | 3.9 | | 4.6 | 4.4 | | | | |
| 05 | 3.7 | | 4.1 | 3.6 | 3.8 | 3.8 | 3.7 | 4.0 | | | 4.3 | | |
| 06 | 4.5 | 4.9 | 3.9 | 4.0 | 3.8 | 3.9 | 4.2 | 4.2 | 44.0 | 4.0 | 4.3 | 4.4 | 3.9 |
| 07 | 4.6 | | 3.8 | 3.8 | 4.3 | 4.2 | 4.7 | 4.4 | 4.9 | 4.1 | 4.4 | | |
| 08 | 4.5 | 4.0 | 3.6 | 3.9 | 4.1 | | | | | | | | |
| 09 | 4.1 | 4.0 | 3.9 | 3.8 | 4.1 | 4.0 | 4.0 | 4.3 | 4.0 | 4.2 | 4.3 | | |
| 10 | 3.5 | 3.7 | 3.9 | 4.0 | 4.0 | 4.2 | 4.0 | 3.9 | 4.0 | 4.3 | 4.0 | | |
| 11 | 3.8 | 3.9 | 3.7 | 4.0 | 4.1 | 4.0 | 3.9 | 3.7 | 3.7 | 3.9 | | | |
| 12 | 4.0 | 4.6 | | 4.1 | 4.4 | 4.3 | 4.3 | 4.1 | 4.3 | 4.1 | 3.9 | | |
| 13 | 4.4 | 4.1 | 4.0 | 3.8 | 3.9 | 3.9 | 4.1 | 3.6 | 3.7 | 4.4 | 3.8 | | |
| 14 | 4.2 | 3.6 | 4.0 | 4.2 | 4.8 | 4.3 | 4.6 | 4.1 | 4.3 | | | | 4.1 |
| 15 | 3.9 | 3.5 | 3.6 | 3.9 | 4.1 | 4.0 | 4.1 | 4.3 | 4.6 | 3.8 | 4.1 | 4.7 | |
| 16 | 5.1 | 4.3 | 4.3 | 4.5 | 4.2 | 4.9 | 4.3 | 4.4 | 4.6 | 4.4 | | | |
| 17 | | 3.8 | 3.6 | | | | | | | | | | |
| 18 | 4.6 | 4.4 | 4.6 | 4.5 | 4.1 | 4.2 | 4.2 | 4.2 | 4.5 | 4.2 | 4.5 | | |
| 19 | 4.0 | 4.2 | 3.8 | 4.2 | 4.1 | 4.4 | 4.0 | 4.2 | 4.2 | | 4.0 | 3.5 | 4.2 |
| 20 | 3.6 | 3.7 | 3.8 | 4.1 | 3.6 | 4.3 | 4.2 | 3.2 | 3.7 | 3.5 | 4.0 | 4.7 | 4.1 |
| 21 | 4.5 | 3.8 | | 4.5 | 4.1 | 4.3 | 4.2 | 4.3 | 4.4 | 4.2 | 4.6 | | 4.5 |
| Summary: | Potassium, mEq/L | | | | | | | | | | | | |
| Average | 4.1 | 4.0 | 4.0 | 4.1 | 4.1 | 4.1 | 4.1 | 4.0 | 4.2 | 4.1 | 4.1 | 4.2 | 4.1 |
| Std Dev | 0.4 | 0.4 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.4 | 0.4 | 0.3 | 0.3 | 0.5 | 0.2 |
| Max | 5.1 | 4.6 | 4.6 | 4.5 | 4.8 | 4.9 | 4.7 | 4.6 | 4.9 | 4.7 | 4.6 | 4.7 | 4.5 |
| Min | 3.5 | 3.5 | 3.6 | 3.6 | 3.6 | 3.8 | 3.7 | 3.2 | 3.6 | 3.5 | 3.6 | 3.5 | 3.9 |

Figure 24: SD & Range Charts for Potassium, mEq/L



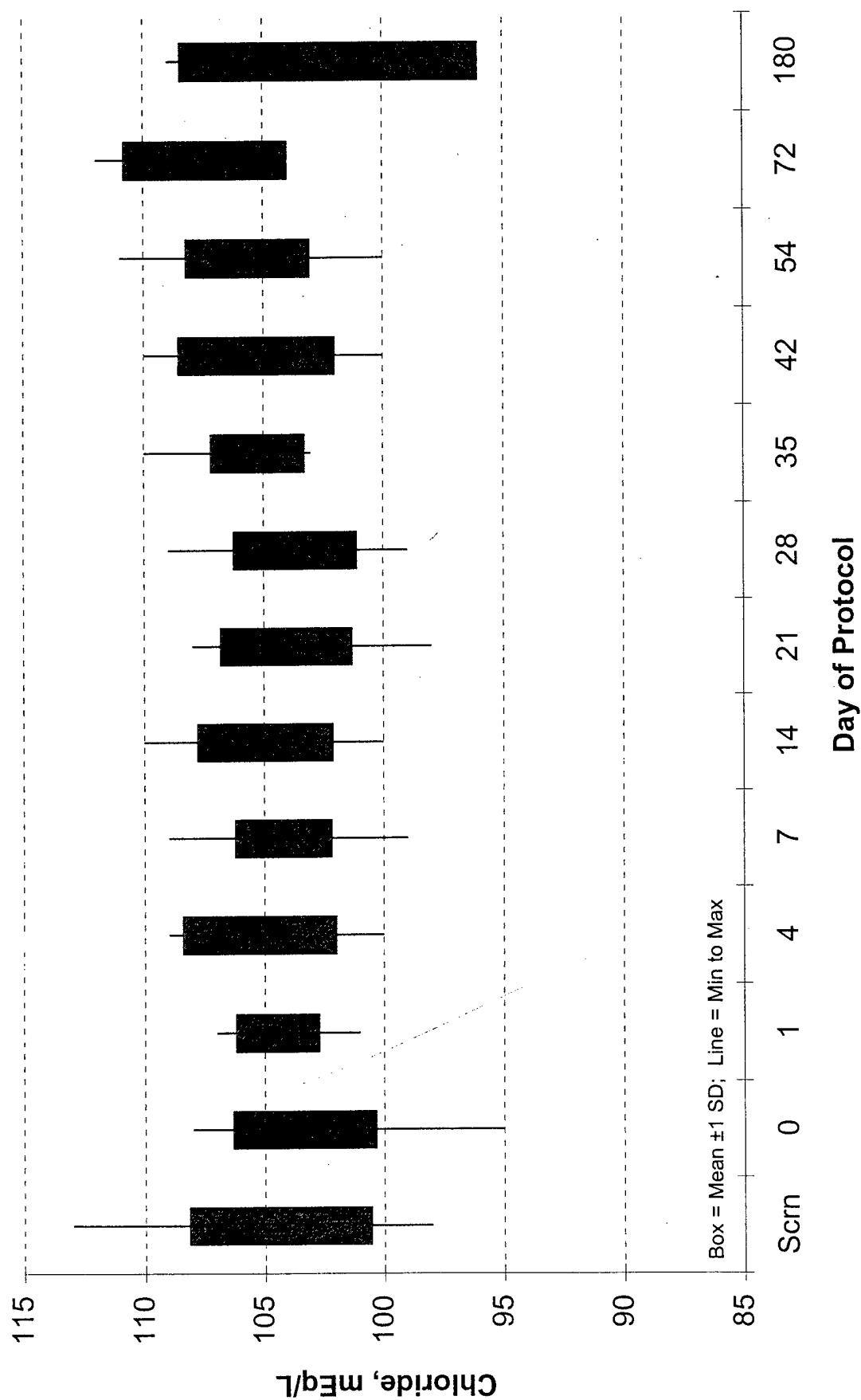
Units: mEq/L

Table 9c
Chloride

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|-----------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 98 | 95 | 101 | 101 | 103 | 105 | 99 | 102 | 105 | 101 | 105 | 108 | 106 |
| 02 | 100 | 99 | 105 | 103 | 103 | 100 | 98 | 101 | 103 | | | | |
| 03 | 107 | 106 | 103 | 105 | 107 | 102 | | 104 | 110 | 106 | 106 | 112 | 109 |
| 04 | 103 | 103 | 104 | 101 | 105 | 105 | | 104 | 104 | | | | |
| 05 | 106 | | 104 | 108 | 109 | 108 | 108 | 106 | | | | | |
| 06 | 103 | 108 | 107 | 106 | 104 | 106 | 105 | 102 | 105 | 100 | 103 | 104 | 98 |
| 07 | 102 | | 106 | 109 | 104 | 108 | 102 | 108 | 105 | 105 | 106 | | |
| 08 | 113 | 105 | 104 | 108 | 104 | | | | | | | | |
| 09 | 113 | 106 | 107 | 108 | 105 | 109 | 105 | 104 | 105 | 104 | 106 | | |
| 10 | 102 | 102 | 106 | 107 | 105 | 109 | 104 | 105 | 106 | 108 | 103 | | |
| 11 | 109 | 106 | 106 | 108 | 104 | 110 | 104 | 104 | | 108 | | | |
| 12 | 103 | 104 | | 104 | 105 | 103 | 106 | 105 | 105 | 107 | 105 | | |
| 13 | 102 | 103 | 103 | 109 | 104 | 104 | 102 | 99 | 105 | 100 | 106 | | |
| 14 | 104 | 104 | 103 | 108 | 103 | 105 | 106 | 107 | 107 | | | | |
| 15 | 103 | 102 | 103 | 107 | 103 | 105 | 106 | 103 | 103 | 110 | 108 | | 96 |
| 16 | 102 | 106 | 107 | 108 | 107 | 104 | 106 | 109 | 109 | 110 | 108 | | |
| 17 | | 101 | 106 | | | | | | | | | | |
| 18 | 102 | 102 | 105 | 100 | 104 | 104 | 101 | 102 | 103 | 106 | 100 | | |
| 19 | 104 | 104 | 104 | 102 | 99 | 104 | 105 | 102 | 106 | | 111 | | |
| 20 | 106 | 104 | 103 | 100 | 102 | 103 | 105 | 103 | 103 | 104 | 107 | 104 | |
| 21 | 105 | | 102 | 102 | 104 | 100 | 107 | 100 | 105 | 105 | 105 | 109 | |
| Summary: | Chloride, mEq/L | | | | | | | | | | | | |
| Average | 104 | 103 | 104 | 105 | 104 | 105 | 104 | 104 | 105 | 105 | 106 | 107 | 102 |
| Std Dev | 04 | 03 | 02 | 03 | 02 | 03 | 03 | 03 | 02 | 03 | 03 | 03 | 06 |
| Max | 113 | 108 | 107 | 109 | 109 | 110 | 108 | 109 | 110 | 110 | 111 | 112 | 109 |
| Min | 98 | 95 | 101 | 100 | 99 | 100 | 98 | 99 | 103 | 100 | 100 | 104 | 96 |

Figure 25: SD & Range Charts for Chloride, mEq/L

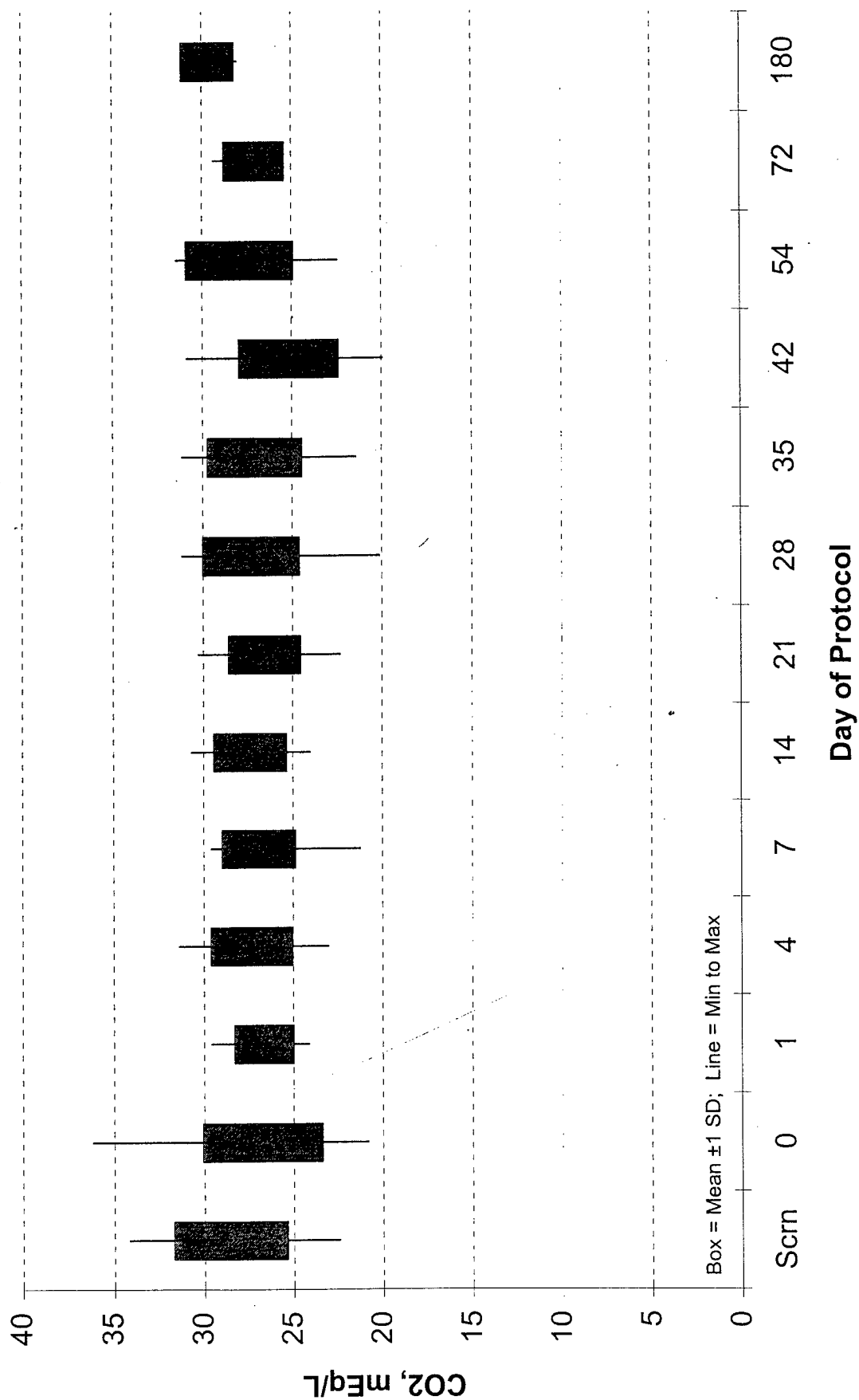


Units: mEq/L

Table 9d
CO₂

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|-------------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 34.2 | 26.4 | 28.8 | 29.8 | 29.5 | 26.9 | 29.0 | 31.2 | 25.4 | 26.3 | 29.9 | 28.0 | 30.9 |
| 02 | 27.1 | 27.7 | 26.0 | 28.5 | 29.4 | 30.0 | 28.2 | 29.3 | 26.7 | | | | |
| 03 | 28.0 | 29.4 | 29.6 | 25.3 | 25.5 | 24.6 | | 28.7 | 25.7 | 19.9 | 22.4 | 25.4 | 28.0 |
| 04 | 24.6 | 36.2 | 27.1 | 27.2 | 27.1 | 28.5 | | 25.3 | 29.0 | | | | |
| 05 | 29.6 | | 25.9 | 28.3 | 28.4 | 29.2 | 27.1 | 30.6 | | | | | |
| 06 | 33.2 | 27.1 | 27.9 | 31.4 | 26.7 | 28.0 | 28.2 | 27.9 | 31.2 | 23.1 | 31.2 | 27.3 | 30.1 |
| 07 | 31.0 | | 27.8 | 23.7 | 26.9 | 28.0 | 25.1 | 29.7 | 26.0 | 29.3 | 25.6 | | |
| 08 | 25.4 | 25.5 | 26.2 | 29.7 | 25.3 | | | | | | | | |
| 09 | 25.2 | 29.5 | 28.3 | 27.2 | 26.0 | 27.8 | 26.7 | 29.6 | 30.4 | 30.9 | 27.5 | | |
| 10 | 22.4 | 20.8 | 24.1 | 23.0 | 21.2 | 24.3 | 24.2 | 24.9 | 23.2 | 24.1 | 22.4 | | |
| 11 | 24.2 | 26.1 | 27.6 | 26.9 | 29.6 | 28.3 | 26.1 | 25.8 | | 26.4 | | | |
| 12 | 29.2 | 26.0 | | 24.0 | 29.0 | 28.4 | 24.9 | 28.5 | 28.6 | 25.2 | 28.8 | | |
| 13 | 27.4 | 28.9 | 27.7 | 28.3 | 27.8 | 30.7 | 28.1 | 26.1 | 25.0 | 25.5 | 29.0 | | |
| 14 | 29.1 | 22.3 | 24.5 | 24.3 | 26.1 | 24.0 | 22.3 | 23.5 | 21.4 | | | | |
| 15 | 31.1 | 27.7 | 29.2 | 29.6 | 27.9 | 25.0 | 25.5 | 29.8 | 27.6 | 25.5 | 31.5 | | |
| 16 | 33.7 | 22.0 | 24.8 | 26.8 | 24.2 | 30.0 | 26.9 | 26.4 | 24.6 | 23.6 | 28.9 | | |
| 17 | | 26.9 | 26.5 | | | | | | | | | | |
| 18 | 27.7 | 27.1 | 25.4 | 28.2 | 28.0 | 24.2 | 24.1 | 26.8 | 29.9 | 27.0 | 29.3 | | |
| 19 | 29.1 | 25.9 | 26.3 | 27.5 | 28.5 | 27.3 | 28.3 | 28.5 | 29.3 | | | | |
| 20 | 28.7 | 25.5 | 24.3 | 26.8 | 24.9 | 27.2 | 26.9 | 20.1 | 28.8 | 23.5 | 25.7 | 25.4 | |
| 21 | 29.5 | | 24.8 | 29.8 | 26.3 | 27.9 | 30.3 | 26.1 | 27.6 | 22.2 | 30.5 | 29.4 | |
| Summary: | CO ₂ , mEq/L | | | | | | | | | | | | |
| Average | 28.5 | 26.7 | 26.6 | 27.3 | 26.9 | 27.4 | 26.6 | 27.3 | 27.1 | 25.2 | 27.9 | 27.1 | 29.7 |
| Std Dev | 03.2 | 03.4 | 01.7 | 02.3 | 02.1 | 02.1 | 02.1 | 02.7 | 02.7 | 02.8 | 03.0 | 01.7 | 01.5 |
| Max | 34.2 | 36.2 | 29.6 | 31.4 | 29.6 | 30.7 | 30.3 | 31.2 | 31.2 | 30.9 | 31.5 | 29.4 | 30.9 |
| Min | 22.4 | 20.8 | 24.1 | 23.0 | 21.2 | 24.0 | 22.3 | 20.1 | 21.4 | 19.9 | 22.4 | 25.4 | 28.0 |

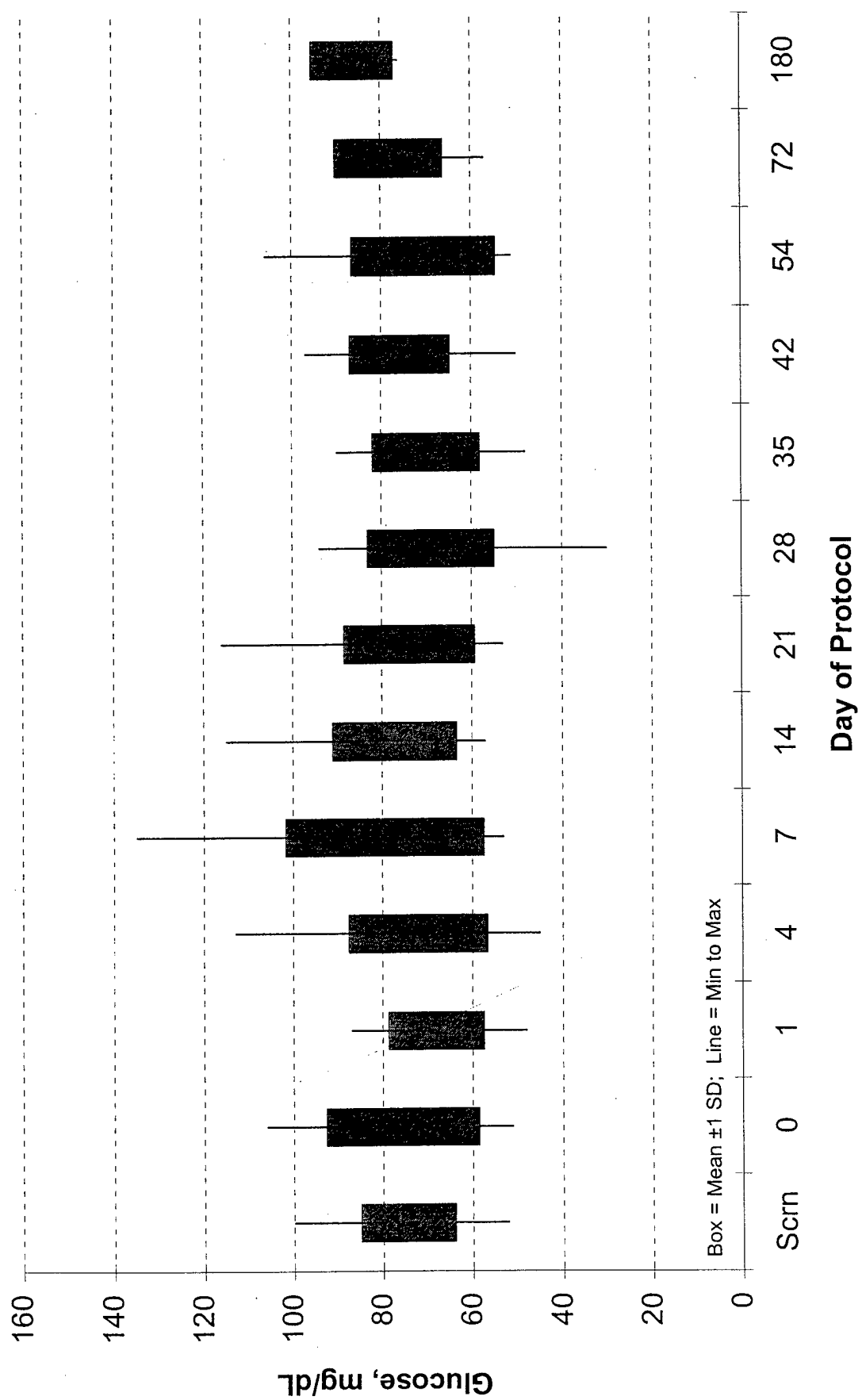
Figure 26: SD & Range Charts for CO₂, mEq/L

Units: mg/dL

Table 9e
Glucose

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------|----------------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 78 | 89 | 70 | 74 | 83 | 91 | 58 | 60 | 63 | 50 | 73 | 83 | 81 |
| 02 | 75 | 82 | 76 | 72 | 94 | 70 | 53 | 56 | 86 | | | | |
| 03 | 71 | 67 | 76 | 74 | 85 | 73 | | 75 | 75 | 77 | 52 | 86 | 76 |
| 04 | 78 | 106 | 76 | 83 | 84 | 91 | | 76 | | | | | |
| 05 | 84 | | 60 | 92 | 69 | 82 | 69 | 82 | | | | | |
| 06 | 80 | 98 | 75 | 57 | 76 | 57 | 82 | 59 | 90 | 74 | 64 | 80 | 95 |
| 07 | 70 | | 65 | 61 | 67 | 84 | 78 | 94 | 57 | 83 | 74 | | |
| 08 | 87 | 77 | 53 | 67 | 53 | | | | | | | | |
| 09 | 67 | 54 | 56 | 63 | 55 | 64 | 60 | 60 | 72 | 66 | 51 | | |
| 10 | 100 | 93 | 81 | 80 | 62 | 115 | 82 | 75 | 88 | 97 | 64 | | |
| 11 | 79 | 80 | 87 | 86 | 74 | 67 | 64 | 68 | | 85 | | | |
| 12 | 84 | 60 | | 45 | 89 | 67 | 83 | 83 | 78 | 81 | 86 | | |
| 13 | 70 | 58 | 64 | 75 | 55 | 77 | 74 | 83 | 65 | 74 | 106 | | |
| 14 | 62 | 67 | 58 | 113 | 89 | 71 | 77 | 65 | 48 | | | | |
| 15 | 64 | 52 | 53 | 67 | 54 | 62 | 116 | 54 | 60 | 62 | 58 | | 93 |
| 16 | 82 | 66 | 65 | 84 | 92 | 78 | 61 | 76 | 75 | 76 | 89 | | |
| 17 | | 51 | 75 | | | | | | | | | | |
| 18 | 66 | 83 | 76 | 74 | 125 | 97 | 63 | 68 | 54 | 82 | 69 | | |
| 19 | 71 | 98 | 70 | 64 | 135 | 75 | 73 | 75 | 68 | | | | |
| 20 | 68 | 80 | 48 | 48 | 61 | 77 | 80 | 30 | 62 | 75 | 76 | 57 | |
| 21 | 52 | | 77 | 62 | 88 | 69 | 83 | 73 | 74 | 80 | 55 | 85 | |
| Summary: | | Glucose, mg/dL | | | | | | | | | | | |
| Average | 74 | 76 | 68 | 72 | 80 | 77 | 74 | 69 | 70 | 76 | 71 | 78 | 86 |
| Std Dev | 11 | 17 | 11 | 16 | 22 | 14 | 15 | 14 | 12 | 11 | 16 | 12 | 09 |
| Max | 100 | 106 | 87 | 113 | 135 | 115 | 116 | 94 | 90 | 97 | 106 | 86 | 95 |
| Min | 52 | 51 | 48 | 45 | 53 | 57 | 53 | 30 | 48 | 50 | 51 | 57 | 76 |

Figure 27: SD & Range Charts for Glucose, mg/dL

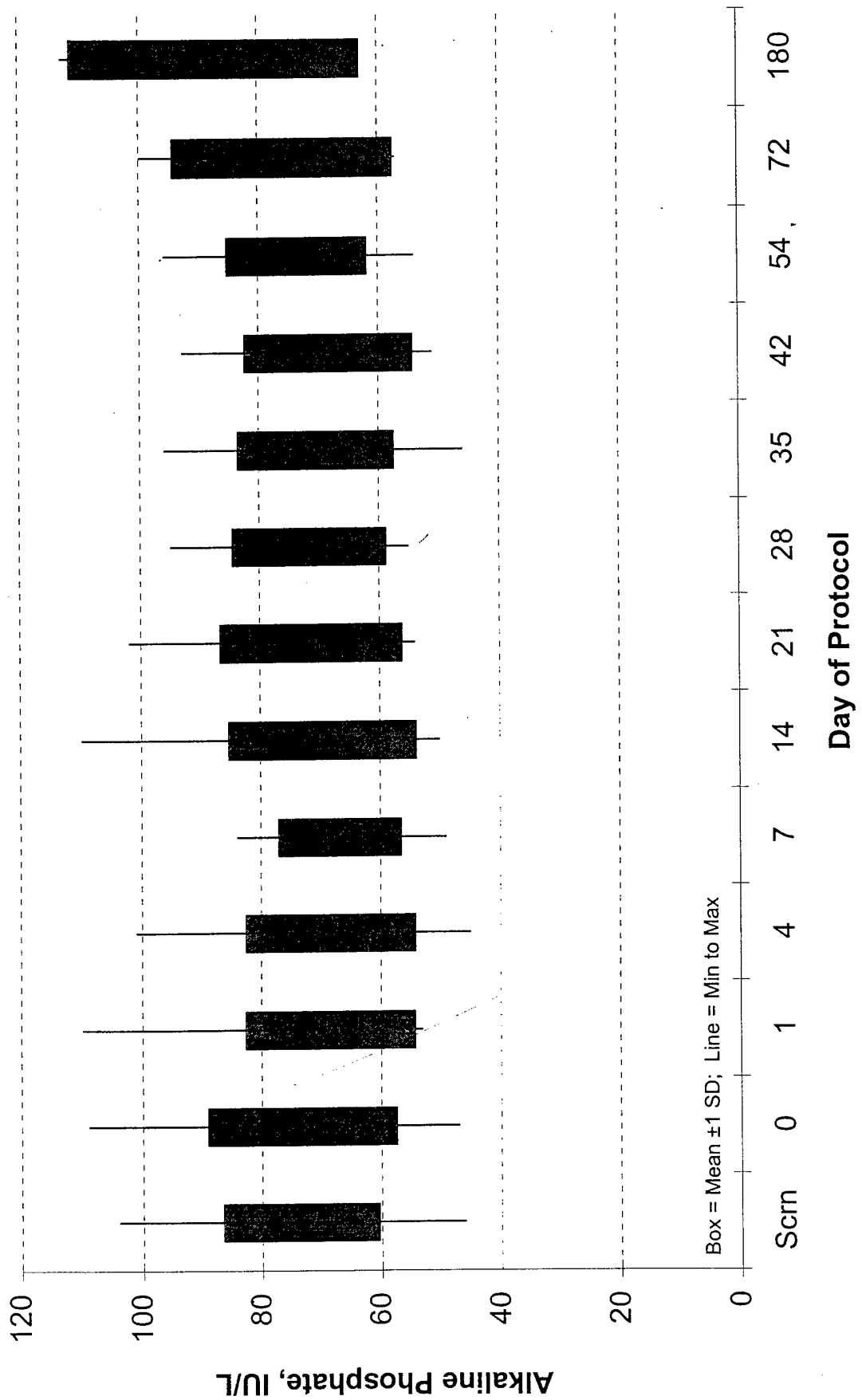
Units: IU/L

Table 10a
Alkaline Phosphatase

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|-----------------------------------|------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 91 | 100 | 89 | 83 | 79 | 90 | 94 | 77 | 88 | 90 | 87 | 88 | 113 |
| 02 | 81 | 86 | 77 | 80 | 75 | 86 | 81 | 95 | 70 | | | | |
| 03 | 46 | 47 | 59 | 45 | 49 | 50 | 54 | 55 | 46 | 51 | 64 | 59 | 65 |
| 04 | 65 | 62 | 54 | | 56 | 55 | | 58 | 66 | | | | |
| 05 | 63 | | 55 | 55 | 59 | 57 | 60 | 70 | | | | | |
| 06 | 77 | 75 | 72 | 67 | 70 | 71 | 77 | 93 | 96 | 93 | 96 | 100 | 103 |
| 07 | 89 | | 70 | 83 | 74 | 72 | 69 | 84 | 73 | 77 | 80 | | |
| 08 | 65 | 60 | 56 | 53 | 53 | | | | | | | | |
| 09 | 67 | 65 | 64 | 69 | 68 | 65 | 73 | 66 | 58 | 61 | 67 | | |
| 10 | 84 | 78 | 72 | 69 | 74 | 85 | 77 | 81 | 87 | 86 | 85 | | |
| 11 | 104 | 109 | 110 | 101 | 84 | 110 | 102 | | 83 | | | | |
| 12 | 67 | 55 | | 53 | 56 | 59 | | 65 | 65 | 65 | 64 | | |
| 13 | 68 | 65 | 57 | 55 | 60 | 64 | 65 | 63 | 58 | 64 | 54 | | |
| 14 | 71 | 77 | 75 | 76 | 76 | 65 | 58 | 59 | | | | | |
| 15 | 72 | 57 | 53 | 56 | 55 | 52 | 55 | | 65 | 53 | 67 | | 68 |
| 16 | 86 | 83 | 80 | 85 | 82 | 88 | 100 | 89 | 80 | 70 | 78 | | |
| 17 | | 81 | | | | | | | | | | | |
| 18 | 61 | 61 | 60 | 64 | 64 | 59 | 57 | 63 | 66 | 63 | 78 | | |
| 19 | 78 | 79 | 70 | 75 | 72 | 75 | 69 | 75 | 76 | | 81 | | |
| 20 | 73 | 78 | 71 | 72 | 69 | 62 | 65 | 70 | 66 | 62 | 69 | 76 | |
| 21 | 61 | | 57 | 58 | 60 | 58 | 59 | 56 | 56 | 53 | 60 | 57 | |
| Summary: Alkaline Phosphate, IU/L | | | | | | | | | | | | | |
| Average | 73 | 73 | 68 | 68 | 67 | 70 | 71 | 72 | 71 | 68 | 74 | 76 | 87 |
| Std Dev | 13 | 16 | 14 | 14 | 10 | 16 | 15 | 13 | 13 | 14 | 12 | 19 | 24 |
| Max | 104 | 109 | 110 | 101 | 84 | 110 | 102 | 95 | 96 | 93 | 96 | 100 | 113 |
| Min | 46 | 47 | 53 | 45 | 49 | 50 | 54 | 55 | 46 | 51 | 54 | 57 | 65 |

Figure 28: SD & Range Charts for Alkaline Phosphate, IU/L



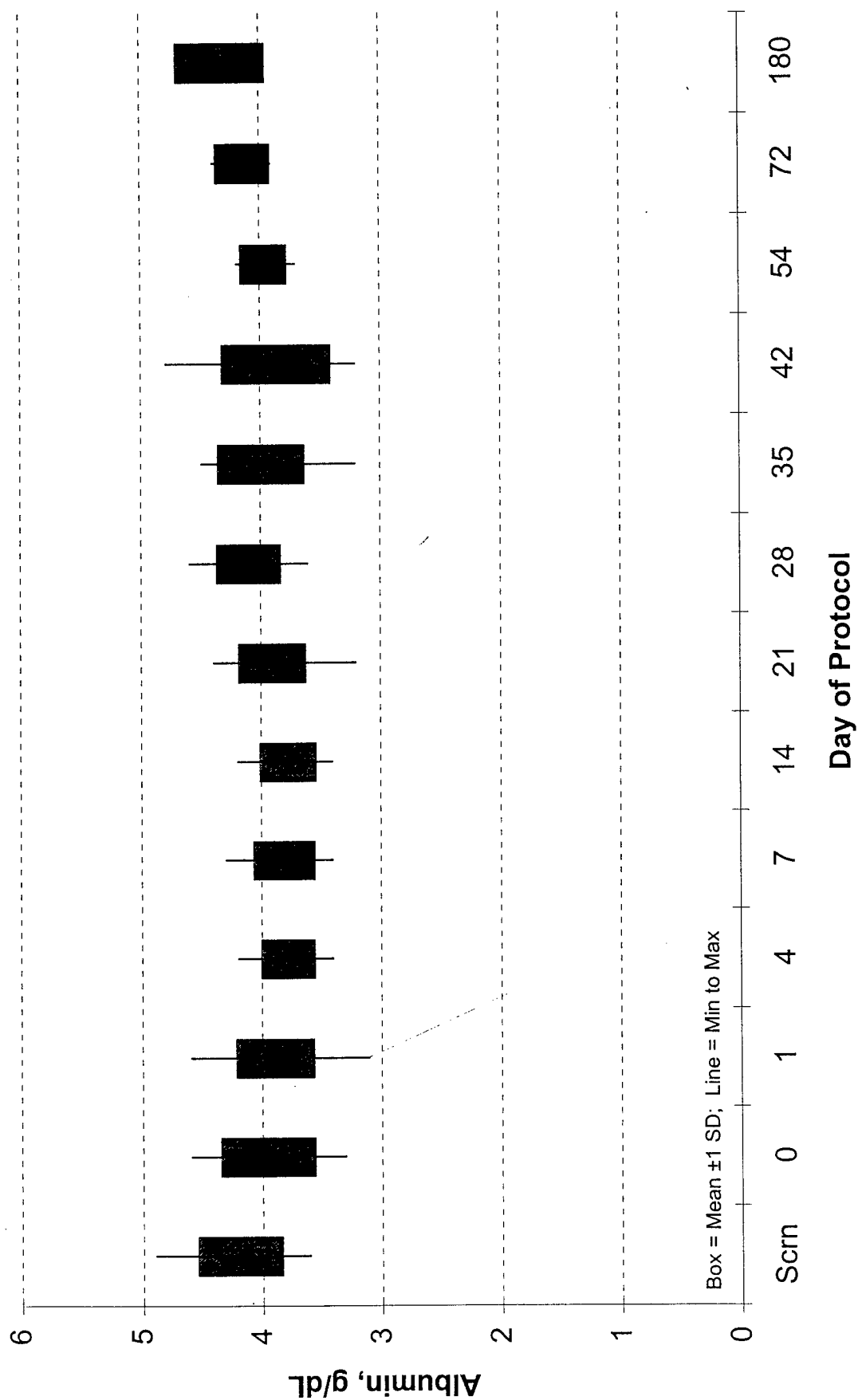
Units: g/dL

Table 10b
Albumin

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|---------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 4.50 | 4.60 | 4.10 | 4.00 | 3.70 | 4.10 | 4.40 | 3.90 | 4.40 | 4.20 | 4.20 | 4.30 | 4.00 |
| 02 | 4.10 | 3.60 | 3.70 | 3.80 | 4.20 | 4.20 | 4.00 | 4.00 | 3.70 | | | | |
| 03 | 4.00 | 3.70 | 4.10 | 3.40 | 3.40 | 3.60 | 4.00 | 4.30 | 3.80 | 4.10 | 3.70 | 3.90 | 4.00 |
| 04 | 4.50 | 4.10 | 4.30 | 4.00 | 3.90 | 3.70 | | 4.20 | 4.30 | | | | |
| 05 | 4.10 | 3.60 | 3.70 | 3.60 | 3.60 | 3.70 | 3.90 | 4.60 | | | | | |
| 06 | 4.30 | 4.50 | 4.30 | 3.90 | 4.10 | 3.70 | 4.20 | 4.30 | 4.50 | 4.20 | 4.10 | 3.90 | 4.60 |
| 07 | 4.30 | 3.90 | 3.90 | 3.90 | 4.30 | | 4.10 | 4.20 | 4.10 | 4.10 | 4.10 | | |
| 08 | 4.40 | 4.10 | 3.80 | 3.80 | 3.90 | | | | | | | | |
| 09 | 3.80 | 3.40 | 3.60 | 3.60 | 3.60 | 3.40 | 3.80 | 3.70 | 3.20 | 3.60 | 3.70 | | |
| 10 | 3.80 | 3.70 | 3.60 | 3.60 | 3.50 | 3.50 | 3.20 | 3.70 | 3.70 | 3.30 | 3.80 | | |
| 11 | 3.80 | 3.70 | 3.90 | 3.50 | 3.80 | 3.70 | 3.60 | 3.90 | 3.50 | | | | |
| 12 | 4.80 | 4.60 | 4.60 | 3.80 | 3.90 | 3.90 | 4.00 | 4.20 | 4.20 | 4.00 | 3.90 | | |
| 13 | 4.20 | 4.40 | 3.90 | 3.60 | 3.80 | 3.60 | 4.00 | 4.00 | 4.30 | 4.80 | 4.20 | | |
| 14 | 3.60 | 3.30 | 3.10 | 3.50 | 3.70 | | 3.60 | 3.60 | 3.60 | | | | |
| 15 | 4.90 | 4.10 | 3.80 | 4.00 | 4.00 | 3.80 | 4.00 | 4.30 | 4.30 | 3.20 | 3.70 | | 4.70 |
| 16 | 3.80 | 3.70 | 3.50 | 3.60 | 3.40 | | | | 3.70 | | | | |
| 17 | | | 4.20 | | | | | | | | | | |
| 18 | 3.80 | 3.70 | 3.60 | 3.70 | 3.50 | 3.50 | 3.60 | | 3.90 | 3.40 | 4.20 | | |
| 19 | 4.30 | 4.30 | 4.00 | 4.10 | 3.90 | 4.00 | 3.90 | 4.20 | 4.30 | | 4.00 | | |
| 20 | 4.50 | 4.10 | 4.00 | 4.20 | 3.90 | 3.90 | 3.90 | 4.40 | 4.20 | 3.70 | 4.10 | 4.40 | |
| 21 | 4.30 | | 4.00 | 4.00 | 4.10 | 4.10 | 4.20 | 4.20 | 4.20 | 3.80 | 3.90 | 4.20 | |
| Summary: | Albumin, g/dL | | | | | | | | | | | | |
| Average | 4.19 | 3.95 | 3.89 | 3.78 | 3.81 | 3.78 | 3.91 | 4.10 | 3.99 | 3.87 | 3.97 | 4.14 | 4.33 |
| Std Dev | 0.36 | 0.40 | 0.33 | 0.23 | 0.26 | 0.24 | 0.28 | 0.27 | 0.37 | 0.46 | 0.20 | 0.23 | 0.38 |
| Max | 4.90 | 4.60 | 4.60 | 4.20 | 4.30 | 4.20 | 4.40 | 4.60 | 4.50 | 4.80 | 4.20 | 4.40 | 4.70 |
| Min | 3.60 | 3.30 | 3.10 | 3.40 | 3.40 | 3.40 | 3.20 | 3.60 | 3.20 | 3.20 | 3.70 | 3.90 | 4.00 |

Figure 29: SD & Range Charts for Albumin, g/dL



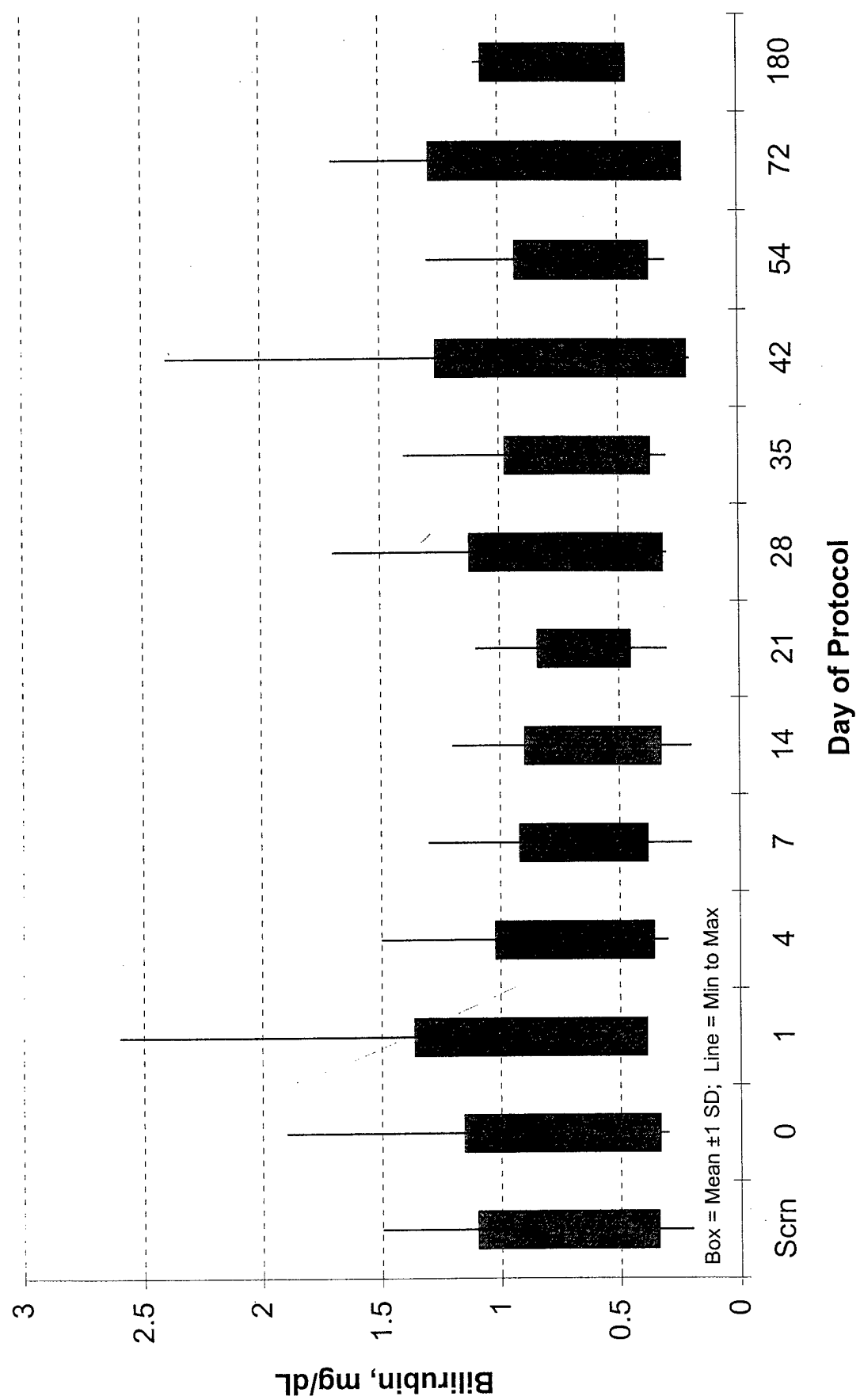
Units: mg/dL

Table 10c
Bilirubin

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 0.4 | 0.6 | 0.8 | 0.5 | 0.6 | 0.5 | 0.7 | 0.6 | 0.6 | 0.7 | 0.5 | 0.4 | 0.70 |
| 02 | 0.6 | 0.7 | 0.5 | 0.5 | 0.6 | 0.5 | 0.5 | 0.7 | 0.4 | | | | |
| 03 | 0.5 | 0.6 | 0.9 | 0.5 | 0.6 | 0.4 | | 0.7 | 0.4 | 0.7 | 0.3 | 0.5 | 0.50 |
| 04 | 0.5 | 0.6 | 0.6 | 0.4 | 0.4 | 0.4 | | 0.3 | 0.4 | 0.5 | | | |
| 05 | 0.6 | | 0.5 | 0.6 | 0.5 | 0.6 | 0.6 | 0.6 | | | | | |
| 06 | 1.0 | 0.8 | 1.1 | 0.4 | 0.7 | 0.7 | 0.8 | 0.8 | 0.8 | 1.3 | 0.8 | 0.6 | 1.10 |
| 07 | 0.6 | | 0.7 | 0.3 | 0.4 | 0.2 | 0.4 | 0.5 | 0.4 | 0.5 | 0.4 | | |
| 08 | 0.5 | 0.6 | 0.6 | 0.5 | 0.5 | | | | | | | | |
| 09 | 0.6 | 0.6 | 0.6 | 0.9 | 0.7 | 0.6 | 0.8 | 0.3 | 0.5 | 0.5 | 0.6 | | |
| 10 | 0.2 | 0.3 | 0.4 | 0.4 | 0.3 | 0.2 | 0.4 | 0.3 | 0.3 | 0.2 | 0.3 | | |
| 11 | 0.7 | 0.3 | 0.6 | 0.4 | 0.6 | 0.6 | 0.9 | 0.5 | | 0.5 | | | |
| 12 | 1.3 | 1.1 | | 1.0 | 0.7 | 0.9 | 0.6 | 0.9 | 0.8 | 0.9 | 0.8 | | |
| 13 | 1.5 | 1.9 | 2.6 | 1.5 | 1.3 | 1.1 | 0.8 | 1.7 | 1.4 | 2.4 | 1.1 | | |
| 14 | 0.8 | 0.7 | 1.0 | 0.8 | 0.7 | 0.6 | 0.6 | 1.0 | 1.0 | | | | |
| 15 | 1.0 | 0.5 | 0.8 | 0.8 | 0.7 | 0.9 | 0.6 | 0.8 | 0.7 | 0.5 | 0.6 | | |
| 16 | 0.3 | 0.5 | 0.8 | 0.8 | 0.7 | 0.9 | 0.6 | 0.8 | 0.7 | 0.5 | 0.6 | | |
| 17 | | 0.8 | 1.0 | | | | | | | | | | |
| 18 | 0.4 | 0.5 | 0.6 | 0.4 | 0.2 | 0.2 | 0.3 | 0.3 | 0.5 | 0.4 | 0.5 | | |
| 19 | 1.0 | 0.7 | 1.0 | 0.9 | 0.7 | 0.6 | 0.6 | 0.8 | 0.8 | | 0.7 | | |
| 20 | 1.5 | 1.6 | 1.6 | 1.4 | 1.3 | 1.2 | 1.1 | 1.7 | 1.2 | 0.9 | 1.3 | 1.7 | |
| 21 | 0.4 | | 0.8 | 0.8 | 0.8 | 0.5 | 0.7 | 0.4 | 0.5 | 0.6 | 0.6 | 0.6 | |
| Summary: | Bilirubin, mg/dL | | | | | | | | | | | | |
| Average | 0.7 | 0.7 | 0.9 | 0.7 | 0.7 | 0.6 | 0.6 | 0.7 | 0.7 | 0.7 | 0.7 | 0.8 | 0.77 |
| Std Dev | 0.4 | 0.4 | 0.5 | 0.3 | 0.3 | 0.3 | 0.2 | 0.4 | 0.3 | 0.5 | 0.3 | 0.5 | 0.31 |
| Max | 1.5 | 1.9 | 2.6 | 1.5 | 1.3 | 1.2 | 1.1 | 1.7 | 1.4 | 2.4 | 1.3 | 1.7 | 1.10 |
| Min | 0.2 | 0.3 | 0.4 | 0.3 | 0.2 | 0.2 | 0.3 | 0.3 | 0.3 | 0.2 | 0.3 | 0.4 | 0.50 |

Figure 30: SD & Range Charts for Bilirubin, mg/dL



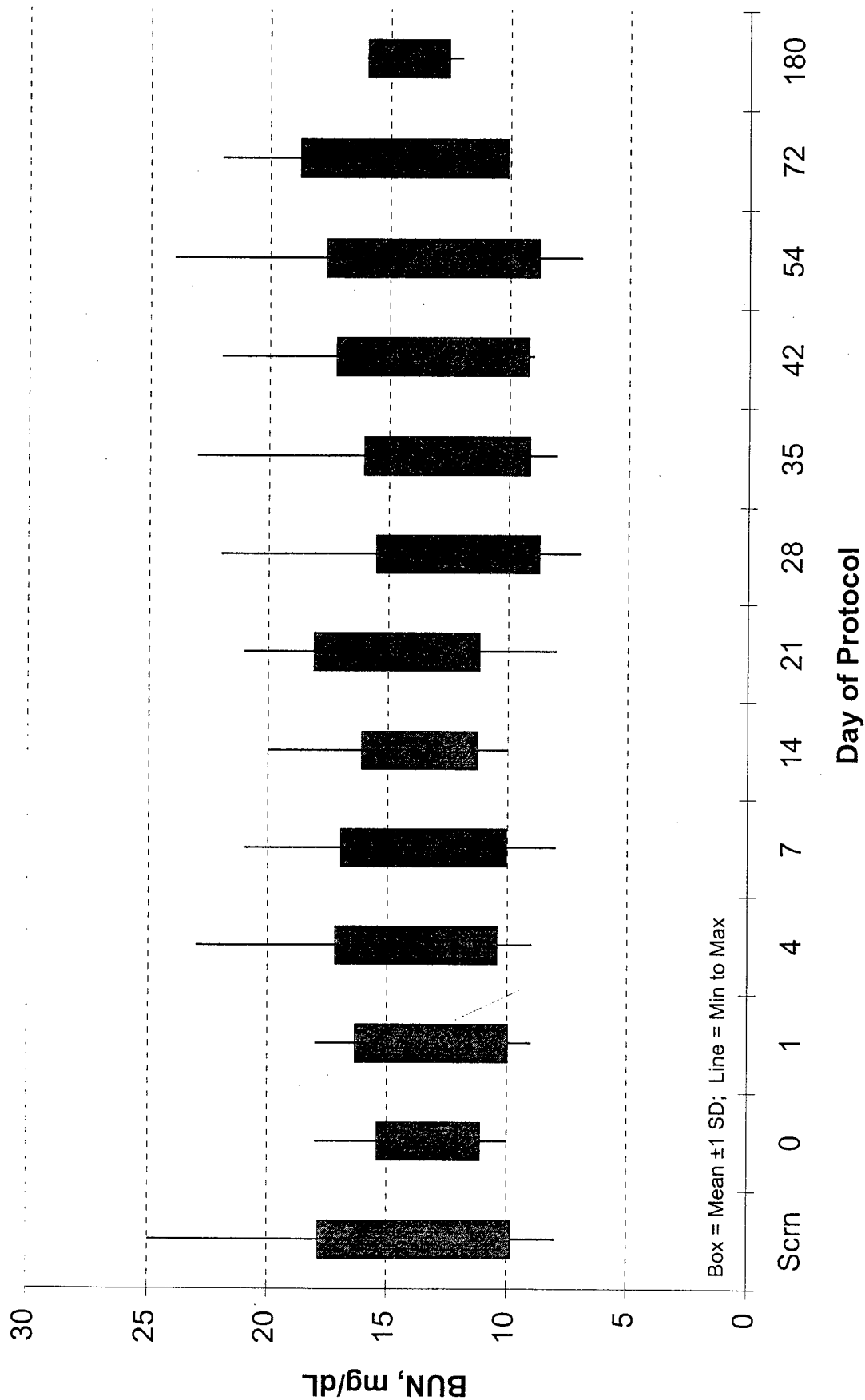
Blank = Not Obtained

Table 10d
BUN

Units: mg/dL

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 16 | 14 | 17 | 10 | 17 | 14 | 18 | 13 | 16 | 15 | 15 | 12 | 12 |
| 02 | 19 | 10 | 10 | 12 | 11 | 12 | 18 | 9 | 8 | | | | |
| 03 | 14 | 17 | 16 | 12 | 11 | 12 | | 12 | 12 | 15 | 14 | 12 | 15 |
| 04 | 14.8 | 11.2 | 16 | 14 | 15 | 11 | | 13 | 12 | | | | |
| 05 | 9 | | 14 | 12 | 12 | 13 | 12 | 8 | | | | | |
| 06 | 11 | 14 | 16 | 18 | 16 | 14 | 15 | 13 | 12 | 17 | 15 | 12 | 14 |
| 07 | 20 | | 10 | 15 | 16 | 20 | 21 | 16 | 10 | 16 | 13 | | |
| 08 | 13 | 14 | 18 | 18 | 20 | | | | | | | | |
| 09 | 14 | 12 | 11 | 14 | 13 | 15 | 14 | 13 | 15 | 18 | 12 | | |
| 10 | 15 | 11 | 11 | 9 | 10 | 18 | 12 | 7 | 12 | 13 | 8 | | |
| 11 | 13 | 12 | 10 | 13 | 10 | 13 | 8 | 10 | | 9 | | | |
| 12 | 10 | 15 | | 12 | 12 | 14 | 14 | 11 | 12 | 10 | 11 | | |
| 13 | 13 | 14 | 17 | 14 | 13 | 13 | 13 | 11 | 13 | 9 | 19 | | |
| 14 | 12 | 14 | 12 | 12 | 11 | 13 | 15 | 15 | 15 | | | | |
| 15 | 12 | 13 | 11 | 13 | 13 | 12 | 11 | 11 | 11 | 10 | 11 | | 16 |
| 16 | 10 | 14 | 13 | 17 | 14 | 13 | 15 | 15 | 12 | 10 | 15 | | |
| 17 | | 10.5 | 9 | | | | | | | | | | |
| 18 | 8 | 14 | 9 | 11 | 8 | 10 | 14 | 12 | 10 | 11 | 7 | | |
| 19 | 16 | 18 | 15 | 17 | 17 | 14 | 18 | 11 | 13 | | 12 | | |
| 20 | 12 | 11 | 10 | 10 | 10 | 12 | 11 | 8.3 | 8 | 10 | 9 | 14.1 | |
| 21 | 25 | | 18 | 23 | 21 | 17 | 20 | 22 | 23 | 22 | 24 | 22 | |
| Summary: | BUN, mg/dL | | | | | | | | | | | | |
| Average | 14 | 13 | 13 | 14 | 14 | 14 | 15 | 12 | 13 | 13 | 13 | 14 | 14 |
| Std Dev | 04 | 02 | 03 | 03 | 03 | 02 | 03 | 03 | 03 | 04 | 04 | 04 | 02 |
| Max | 25 | 18 | 18 | 23 | 21 | 20 | 21 | 22 | 23 | 22 | 24 | 22 | 16 |
| Min | 08 | 10 | 09 | 09 | 08 | 10 | 08 | 07 | 08 | 09 | 07 | 12 | 12 |

Figure 31: SD & Range Charts for BUN, mg/dL



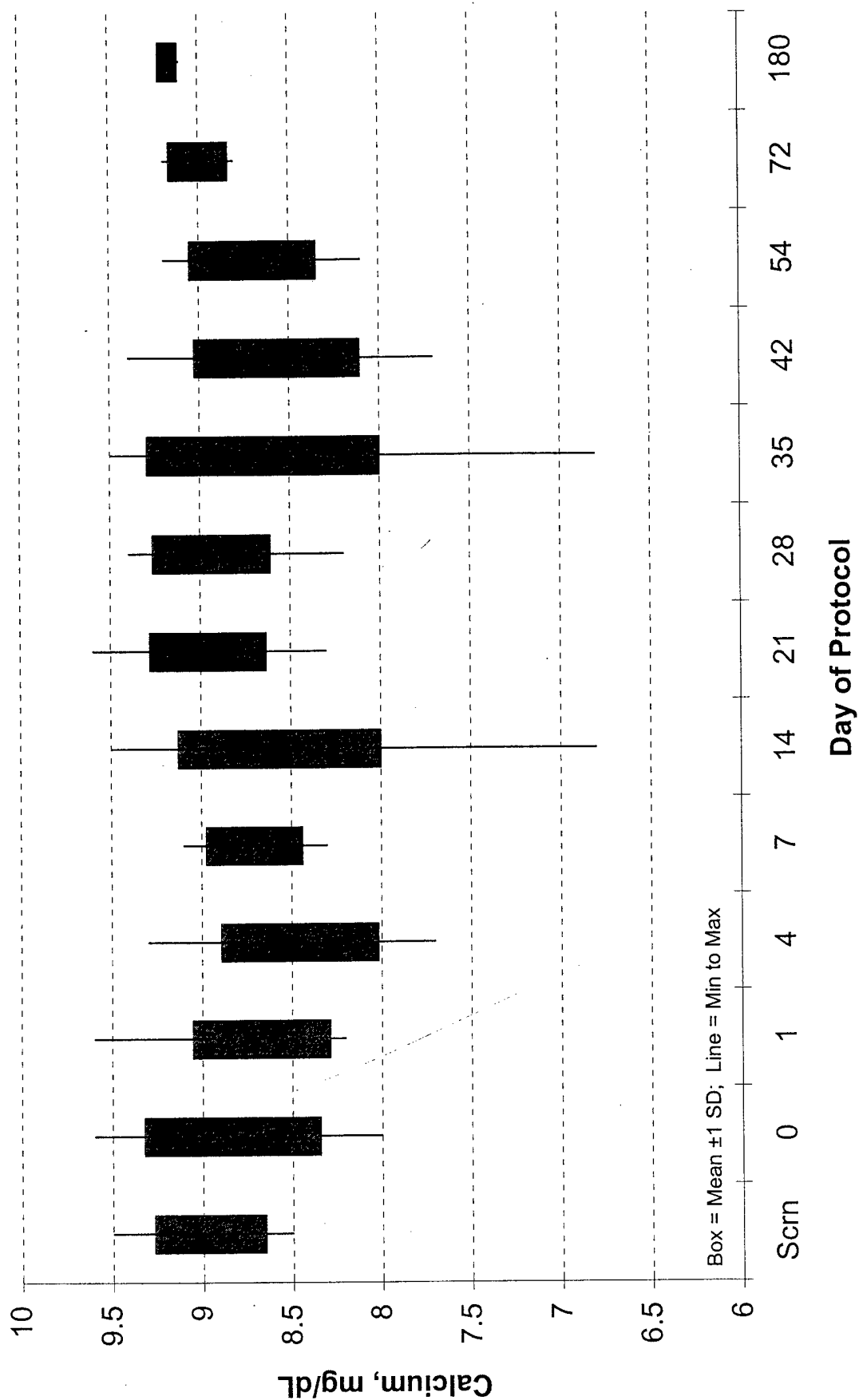
Units: mg/dL

Table 10e
Calcium

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|----------------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | 9.40 | 9.30 | 8.90 | 8.50 | 8.70 | 8.80 | 9.10 | 8.80 | 9.10 | 8.30 | 8.60 | 8.90 | 9.20 |
| 02 | 9.20 | 9.20 | 9.20 | 8.80 | 9.10 | 9.50 | 9.30 | 9.40 | 8.40 | | | | |
| 03 | 9.30 | 9.30 | 9.60 | 8.30 | 8.90 | 6.80 | | 9.10 | 8.40 | 9.00 | 8.70 | 9.20 | 9.20 |
| 04 | 9.10 | 8.70 | 9.10 | 8.70 | 8.70 | 8.60 | | 9.20 | 8.80 | 9.00 | | | |
| 05 | 8.80 | | 8.30 | 8.40 | 8.30 | 8.20 | 8.50 | 9.10 | | | | | |
| 06 | 9.10 | 9.40 | 8.60 | 8.30 | 8.50 | 7.80 | 9.20 | 9.30 | 9.10 | 8.80 | 8.70 | 8.80 | 9.10 |
| 07 | 9.00 | | 8.60 | 8.30 | 8.90 | 8.70 | 9.10 | 9.10 | 8.70 | 8.80 | 8.50 | | |
| 08 | 9.00 | 8.90 | 8.50 | 7.80 | 8.40 | | | | | | | | |
| 09 | 8.60 | 8.70 | 8.20 | 7.90 | 8.60 | 8.70 | 9.00 | 8.70 | 7.60 | 8.50 | 8.80 | | |
| 10 | 8.50 | 8.90 | 8.60 | 7.70 | 8.60 | 8.50 | 8.70 | 8.60 | 8.30 | 8.50 | 9.00 | | |
| 11 | 8.50 | 8.30 | 8.20 | 8.10 | 8.80 | 8.20 | 8.60 | 8.20 | | 8.00 | | | |
| 12 | 9.50 | 9.50 | | 8.80 | 9.10 | 9.00 | 9.30 | 9.40 | 9.50 | 9.10 | 9.20 | | |
| 13 | 9.00 | 8.90 | 9.10 | 8.10 | 8.30 | 8.70 | 9.60 | 8.70 | 9.00 | 9.40 | 9.00 | | |
| 14 | 8.70 | 8.20 | 8.30 | 8.90 | 8.90 | 8.70 | 9.00 | 9.00 | 8.60 | | | | |
| 15 | 9.10 | 8.60 | 8.60 | 8.20 | 8.90 | 8.70 | 8.80 | 8.90 | 9.00 | 7.70 | 8.10 | | |
| 16 | 8.60 | 8.00 | 8.40 | 8.30 | 8.40 | 8.60 | 8.90 | 8.40 | 8.50 | 8.30 | 8.10 | | |
| 17 | | 9.60 | 8.70 | | | | | | | | | | |
| 18 | 9.30 | 8.70 | 9.10 | 9.30 | 9.10 | 8.70 | 9.20 | 8.80 | 9.00 | 8.70 | 9.20 | | |
| 19 | 9.10 | 8.80 | 8.70 | 9.20 | 8.80 | 9.30 | 8.90 | 9.30 | 9.00 | | 8.80 | | |
| 20 | 8.50 | 8.00 | 8.30 | 8.70 | 8.30 | 8.50 | 8.30 | 9.00 | 6.80 | 8.30 | 8.30 | 8.80 | |
| 21 | 8.90 | | 8.40 | 8.80 | 8.80 | 8.70 | 8.80 | 8.80 | 9.20 | 8.10 | 8.80 | 9.00 | |
| Summary: | Calcium, mg/dL | | | | | | | | | | | | |
| Average | 8.96 | 8.83 | 8.67 | 8.46 | 8.71 | 8.56 | 8.96 | 8.94 | 8.65 | 8.57 | 8.70 | 9.00 | 9.17 |
| Std Dev | 0.31 | 0.49 | 0.38 | 0.44 | 0.27 | 0.57 | 0.33 | 0.33 | 0.65 | 0.46 | 0.36 | 0.17 | 0.06 |
| Max | 9.50 | 9.60 | 9.60 | 9.30 | 9.10 | 9.50 | 9.60 | 9.40 | 9.50 | 9.40 | 9.20 | 9.20 | 9.20 |
| Min | 8.50 | 8.00 | 8.20 | 7.70 | 8.30 | 6.80 | 8.30 | 8.20 | 6.80 | 7.70 | 8.10 | 8.80 | 9.10 |

Figure 32: SD & Range Charts for Calcium, mg/dL



Units: mg/dL

Table 10f
Cholesterol

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|--------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 200 | 229 | 210 | 198 | 192 | 201 | 210 | 192 | 207 | 188 | 185 | 225 | 184 |
| 02 | | 186 | 167 | 165 | 169 | 177 | 170 | 150 | 118 | | | | |
| 03 | 207 | 187 | 225 | 171 | 168 | 175 | 207 | 203 | 167 | 175 | 137 | 146 | 126 |
| 04 | 191 | 154 | 164 | 179 | 173 | 173 | | 171 | 160 | | | | |
| 05 | 101 | | 92 | 97 | 97 | 101 | 105 | 90 | | | | | |
| 06 | 191 | 182 | 175 | 172 | 188 | 172 | 201 | 196 | 182 | 177 | 163 | 155 | 176 |
| 07 | 364 | 308 | 297 | 288 | 326 | 424 | 484 | 440 | 381 | 349 | 171 | | |
| 08 | 192 | 191 | 186 | 195 | 194 | | | | | | | | |
| 09 | 202 | 188 | 189 | 200 | 204 | 187 | 214 | 189 | 154 | 182 | 209 | | |
| 10 | 179 | 164 | 166 | 153 | 158 | 171 | 172 | 171 | 163 | 163 | 171 | | |
| 11 | 217 | 188 | 186 | 170 | 191 | 158 | 207 | 178 | 192 | | | | |
| 12 | 242 | 231 | | 224 | 222 | 225 | 232 | 225 | 234 | 206 | 201 | | |
| 13 | 177 | 183 | 177 | 167 | 162 | 159 | 179 | 160 | 165 | 182 | 166 | | |
| 14 | 214 | 193 | 185 | 212 | 220 | 206 | 214 | 218 | 220 | | | | |
| 15 | 206 | 173 | 184 | 197 | 202 | 213 | 193 | 200 | 201 | 192 | 225 | | |
| 16 | 173 | 172 | 175 | 175 | 156 | 161 | 166 | 172 | 180 | 157 | 164 | | |
| 17 | | | | | | | | | | | | | |
| 18 | 206 | 173 | 184 | 197 | 202 | 213 | 193 | 200 | 201 | 192 | 225 | | |
| 19 | 217 | 199 | 196 | 219 | 207 | 201 | 199 | 195 | 222 | 217 | 206 | | |
| 20 | 118 | 117 | 118 | 114 | 132 | 121 | 141 | 138 | 127 | 109 | 105 | 125 | |
| 21 | 184 | | 197 | 199 | 198 | 189 | 217 | 199 | 209 | 183 | 185 | 186 | |
| Summary: | Cholesterol, mg/dL | | | | | | | | | | | | |
| Average | 199 | 190 | 183 | 185 | 188 | 191 | 206 | 194 | 194 | 191 | 180 | 167 | 162 |
| Std Dev | 52 | 39 | 40 | 40 | 44 | 64 | 76 | 67 | 57 | 52 | 33 | 39 | 31 |
| Max | 364 | 308 | 297 | 288 | 326 | 424 | 484 | 440 | 381 | 349 | 225 | 225 | 184 |
| Min | 101 | 117 | 92 | 97 | 97 | 101 | 105 | 90 | 118 | 109 | 105 | 125 | 126 |

Figure 33: SD & Range Charts for Cholesterol, mg/dL

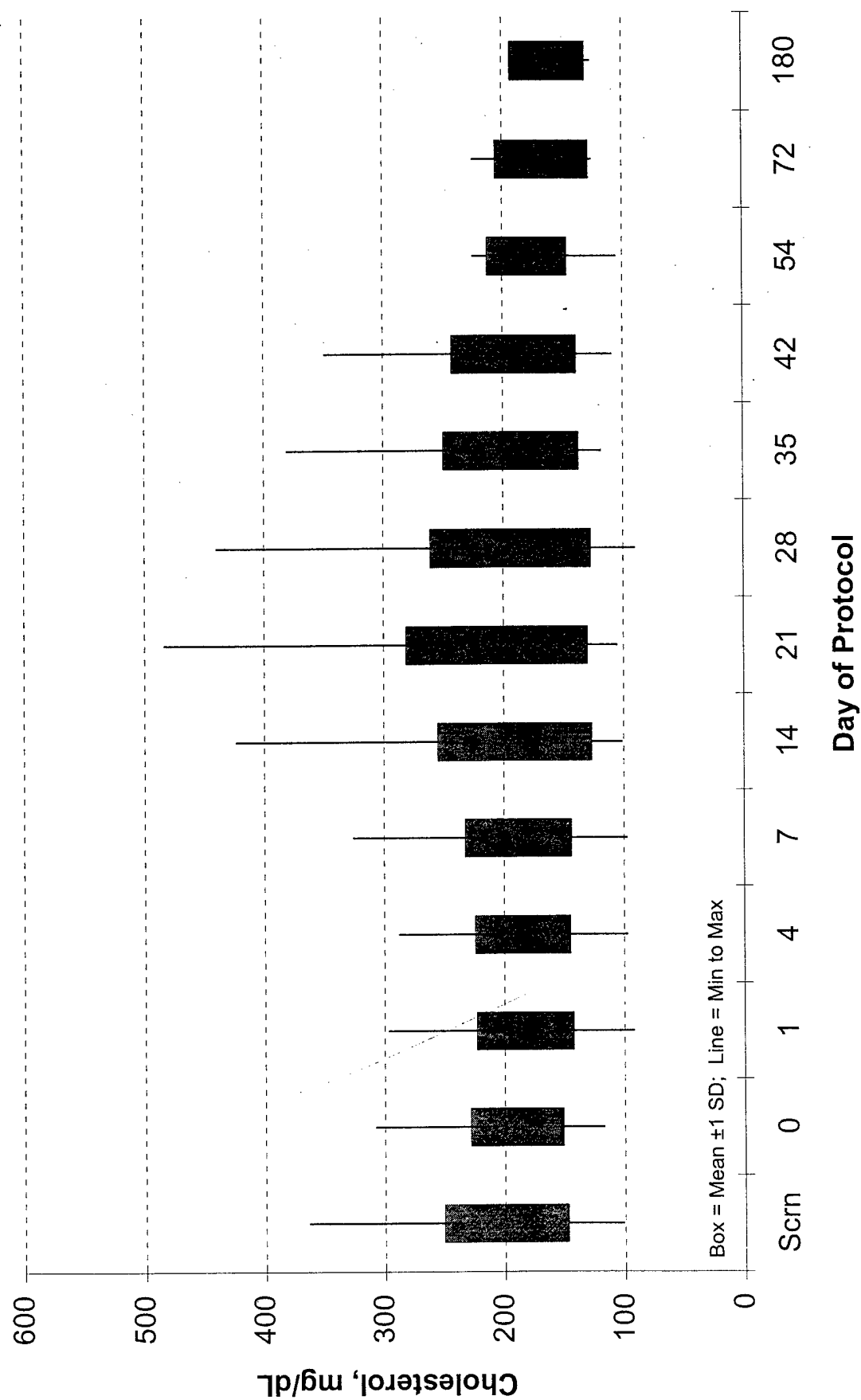


Table 10g
HDL

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|--------------|------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | | 57 | 47 | 41 | 32 | | 42 | 50 | 54 | 47 | 39 | | 38 |
| 02 | | 40 | 40 | 38 | 36 | | 40 | 42 | 36 | | | | |
| 03 | | 66 | 79 | 54 | | | 52 | 72 | 71 | 47 | 53 | 61 | 50 |
| 04 | 50 | | | 55 | 60 | | | 41 | 44 | | | | |
| 05 | | | 39 | 44 | 44 | 43 | 47 | 49 | | | | | |
| 06 | | 38 | 38 | 37 | 85 | 32 | 33 | 36 | | 32 | 36 | 35 | 29 |
| 07 | 48 | | 47 | 46 | 54 | | 55 | | 43 | 48 | 50 | | |
| 08 | | 44 | 46 | | | 54 | | | | | | | |
| 09 | | 42 | 48 | 42 | 40 | | 41 | 48 | 41 | 45 | 52 | | |
| 10 | | 47 | 56 | 45 | 46 | 51 | 53 | 59 | 49 | 43 | 57 | | |
| 11 | 55 | 57 | 59 | | 37 | 48 | 49 | 55 | | | | | |
| 12 | | 65 | | 55 | 52 | 52 | 38 | 56 | 64 | 56 | 54 | | |
| 13 | | | 54 | 44 | 51 | 41 | 51 | 48 | 50 | | | | |
| 14 | | 60 | 63 | 58 | 73 | 72 | 83 | 92 | 86 | | | | |
| 15 | | 64 | 61 | 63 | 64 | 66 | 62 | 74 | 61 | 82 | 89 | | |
| 16 | | 58 | 61 | 58 | 60 | 57 | 61 | 66 | 66 | 71 | 60 | | |
| 17 | | 39 | | | | | | | | | | | |
| 18 | | 64 | 61 | 63 | 64 | 66 | 62 | | 61 | 83 | 89 | | |
| 19 | | 64 | 61 | 63 | 64 | 66 | 62 | 74 | 61 | 82 | 89 | | |
| 20 | | 44 | 47 | 38 | 36 | 38 | 49 | 46 | 55 | 45 | 46 | | |
| 21 | 63 | | 59 | 40 | 41 | 47 | 41 | 50 | 62 | 55 | 59 | | |
| Summary: HDL | | | | | | | | | | | | | |
| Average | 54 | 53 | 54 | 49 | 52 | 52 | 51 | 56 | 57 | 57 | 59 | 48 | 39 |
| Std Dev | 07 | 11 | 11 | 09 | 15 | 12 | 12 | 15 | 13 | 17 | 18 | 18 | 11 |
| Max | 63 | 66 | 79 | 63 | 85 | 72 | 83 | 92 | 86 | 83 | 89 | 61 | 50 |
| Min | 48 | 38 | 38 | 37 | 32 | 32 | 33 | 36 | 36 | 32 | 36 | 35 | 29 |

Figure 34: SD & Range Charts for HDL

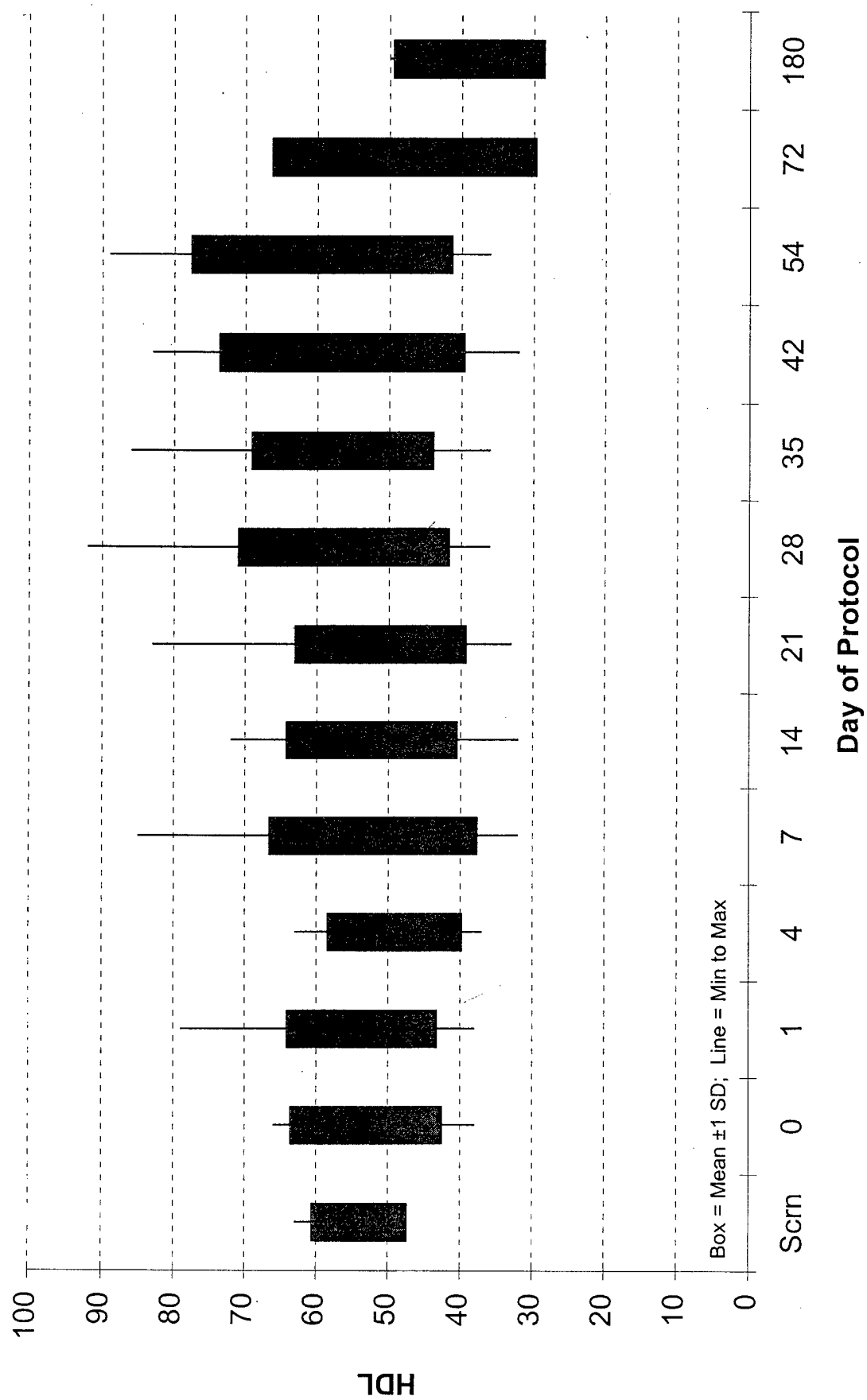
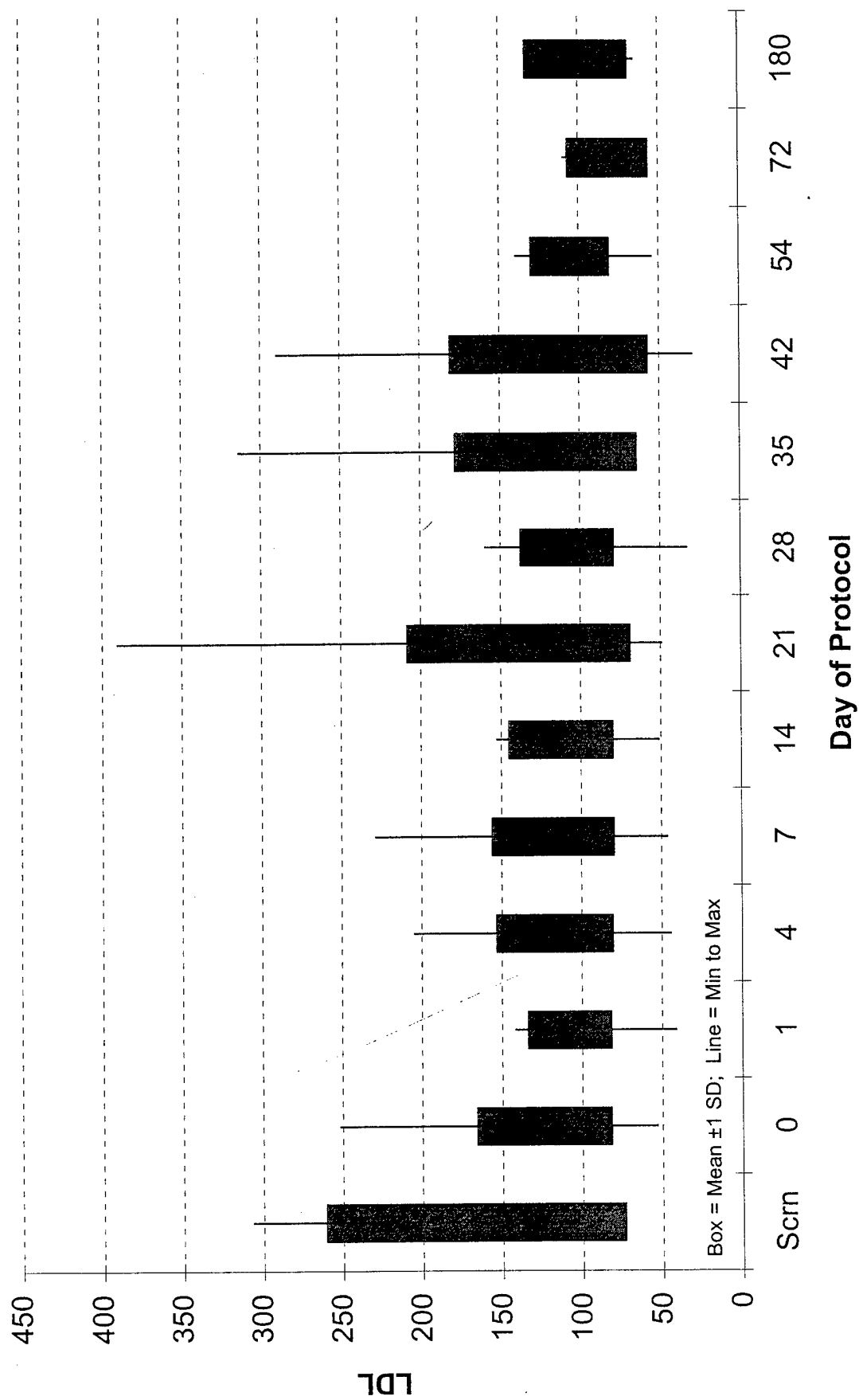


Table 10h
LDL

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|--------------|------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | | 150 | 142 | 126 | 121 | | 147 | 130 | 132 | 128 | 119 | | 111 |
| 02 | | 124 | 114 | 105 | 114 | | 111 | 80 | 66 | | | | |
| 03 | | 111 | 135 | 106 | | | 148 | 116 | 88 | 116 | 73 | 75 | 65 |
| 04 | 119 | | | 95 | 102 | | | 122 | 107 | | | | |
| 05 | | | 41 | 44 | 46 | | 49 | 33 | | | | | |
| 06 | | 123 | 117 | 122 | 83 | 126 | 147 | 146 | | 29 | 118 | 110 | 128 |
| 07 | 307 | 252 | | 205 | 229 | | 391 | | 314 | 290 | 86 | | |
| 08 | | 131 | 122 | | 129 | | | | | | | | |
| 09 | | 130 | 123 | 140 | 143 | | 157 | 127 | 94 | 122 | 138 | | |
| 10 | | 102 | 98 | 97 | 101 | 99 | 104 | 99 | 98 | 94 | 102 | | |
| 11 | 133 | 118 | 118 | | 117 | 57 | 127 | 109 | | | | | |
| 12 | | 154 | | 139 | 150 | 153 | 181 | 160 | 155 | 136 | 122 | | |
| 13 | | | 106 | 103 | 98 | 101 | 103 | 93 | 102 | | | | |
| 14 | | 122 | 114 | 145 | 134 | 125 | 122 | 113 | 125 | | | | |
| 15 | | 83 | 102 | 120 | 118 | 134 | 123 | 91 | 102 | 87 | 117 | | |
| 16 | | 95 | 103 | 102 | 83 | 92 | 85 | 95 | 101 | 78 | 92 | | |
| 17 | | 150 | | | | | | | | | | | |
| 18 | | 83 | 102 | 120 | 118 | 134 | 123 | 91 | 102 | 87 | 117 | | |
| 19 | | 125 | 127 | 153 | 141 | 139 | 112 | 132 | 151 | 145 | 140 | | |
| 20 | | 53 | 49 | 48 | 67 | 51 | 105 | 79 | 70 | | 54 | 60 | |
| 21 | 109 | | 119 | 133 | 143 | 140 | 162 | 133 | 134 | 118 | 97 | | |
| Summary: LDL | | | | | | | | | | | | | |
| Average | 167 | 124 | 108 | 117 | 118 | 113 | 139 | 108 | 121 | 119 | 106 | 82 | 101 |
| Std Dev | 94 | 42 | 26 | 37 | 39 | 33 | 70 | 29 | 57 | 62 | 25 | 26 | 33 |
| Max | 307 | 252 | 142 | 205 | 229 | 153 | 391 | 160 | 314 | 290 | 140 | 110 | 128 |
| Min | 109 | 53 | 41 | 44 | 46 | 51 | 49 | 33 | 66 | 29 | 54 | 60 | 65 |

Figure 35: SD & Range Charts for LDL



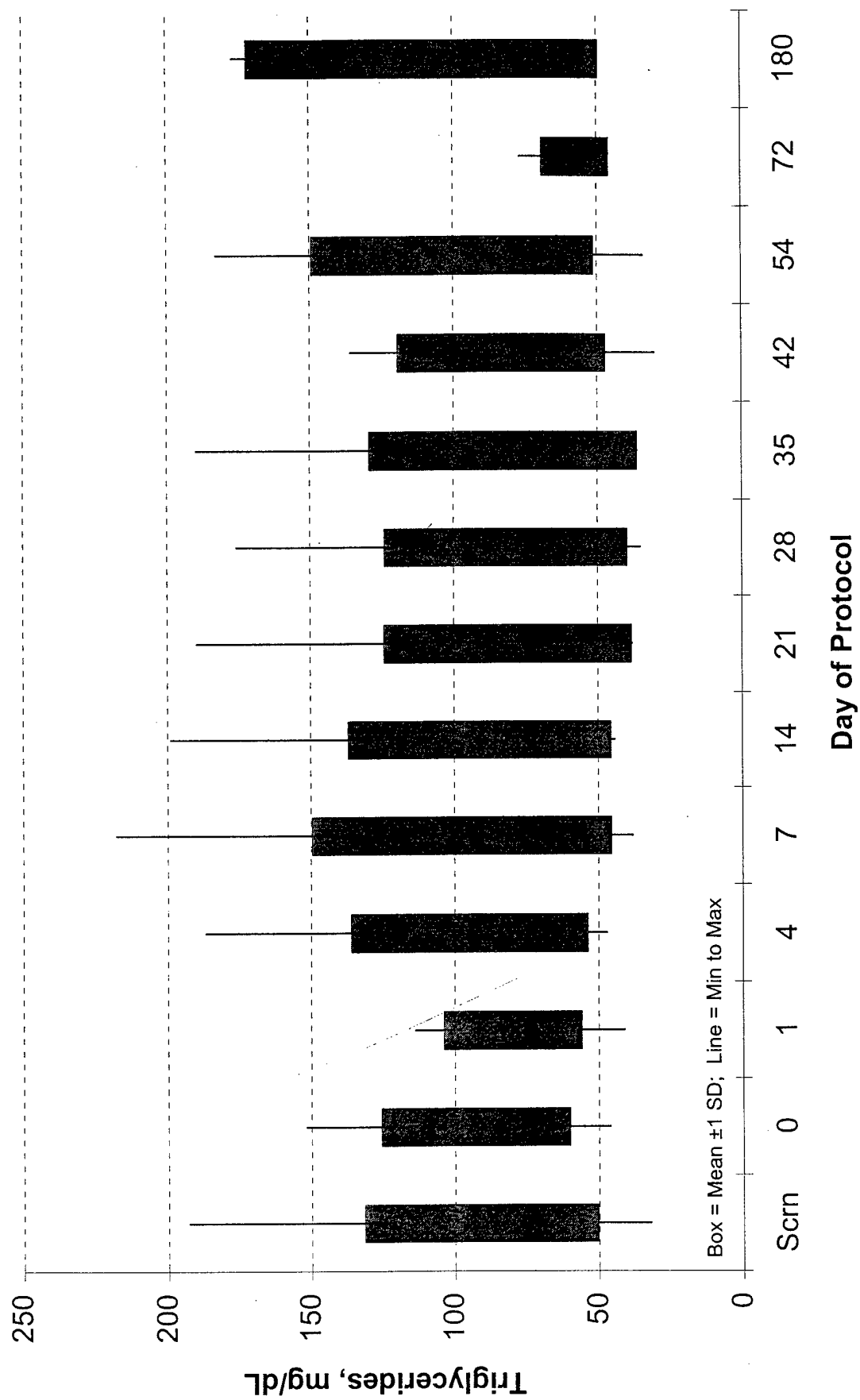
Units: mg/dL

Table 10i
Triglycerides

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|----------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 91 | 110 | 107 | 155 | 197 | 167 | 107 | 64 | 108 | 68 | 136 | 77 | 177 |
| 02 | | 109 | 69 | 113 | 96 | 113 | 95 | 143 | 82 | | | | |
| 03 | 65 | 50 | 57 | 55 | 56 | 79 | 38 | 75 | 41 | 64 | 57 | 53 | 56 |
| 04 | 114 | 125 | 50 | 146 | 56 | 165 | | 42 | 46 | | | | |
| 05 | 66 | | 60 | 47 | 38 | 44 | 46 | 42 | | | | | |
| 06 | 59 | 106 | 100 | 67 | 101 | 70 | 100 | 70 | 57 | 83 | 46 | 50 | 99 |
| 07 | 45 | 47 | 41 | 187 | 218 | 199 | 190 | 35 | 124 | 55 | 179 | | |
| 08 | 62 | 83 | 90 | 59 | 57 | | | | | | | | |
| 09 | 55 | 80 | 94 | 91 | 105 | 84 | 81 | 73 | 48 | 76 | 99 | | |
| 10 | 94 | 78 | 64 | 59 | 57 | 108 | 78 | 69 | 84 | 134 | 60 | | |
| 11 | 145 | 118 | 96 | 123 | 187 | | | | | | | | |
| 12 | 95 | 60 | | 101 | 103 | 65 | 49 | 77 | 74 | 127 | | | |
| 13 | 193 | 88 | 87 | 104 | 69 | 86 | 128 | 95 | 69 | 61 | 183 | | |
| 14 | 126 | 56 | 41 | 48 | 65 | 45 | 46 | 67 | 46 | | | | |
| 15 | 102 | 134 | 108 | 73 | 102 | 65 | 44 | 176 | 190 | 118 | 97 | | |
| 16 | 73 | 95 | 58 | 78 | 69 | 62 | 104 | 57 | 66 | 42 | 63 | | |
| 17 | | | | | | | | | | | | | |
| 18 | 102 | 134 | 108 | 73 | 102 | 65 | 44 | 176 | 190 | 118 | 97 | | |
| 19 | 147 | 152 | 114 | 140 | 152 | 122 | 139 | 89 | 81 | 136 | 104 | | |
| 20 | 32 | 46 | 78 | 47 | 47 | 48 | 47 | 41 | 36 | 30 | 34 | 48 | |
| 21 | 62 | | 95 | 132 | 73 | 55 | 47 | 84 | 66 | 54 | 149 | 60 | |
| Summary: | Triglycerides, mg/dL | | | | | | | | | | | | |
| Average | 91 | 93 | 80 | 95 | 98 | 91 | 81 | 82 | 83 | 83 | 100 | 58 | 111 |
| Std Dev | 41 | 33 | 24 | 41 | 52 | 46 | 43 | 42 | 47 | 36 | 49 | 12 | 61 |
| Max | 193 | 152 | 114 | 187 | 218 | 199 | 190 | 176 | 190 | 136 | 183 | 77 | 177 |
| Min | 32 | 46 | 41 | 47 | 38 | 44 | 38 | 35 | 36 | 30 | 34 | 48 | 56 |

Figure 36: SD & Range Charts for Triglycerides, mg/dL



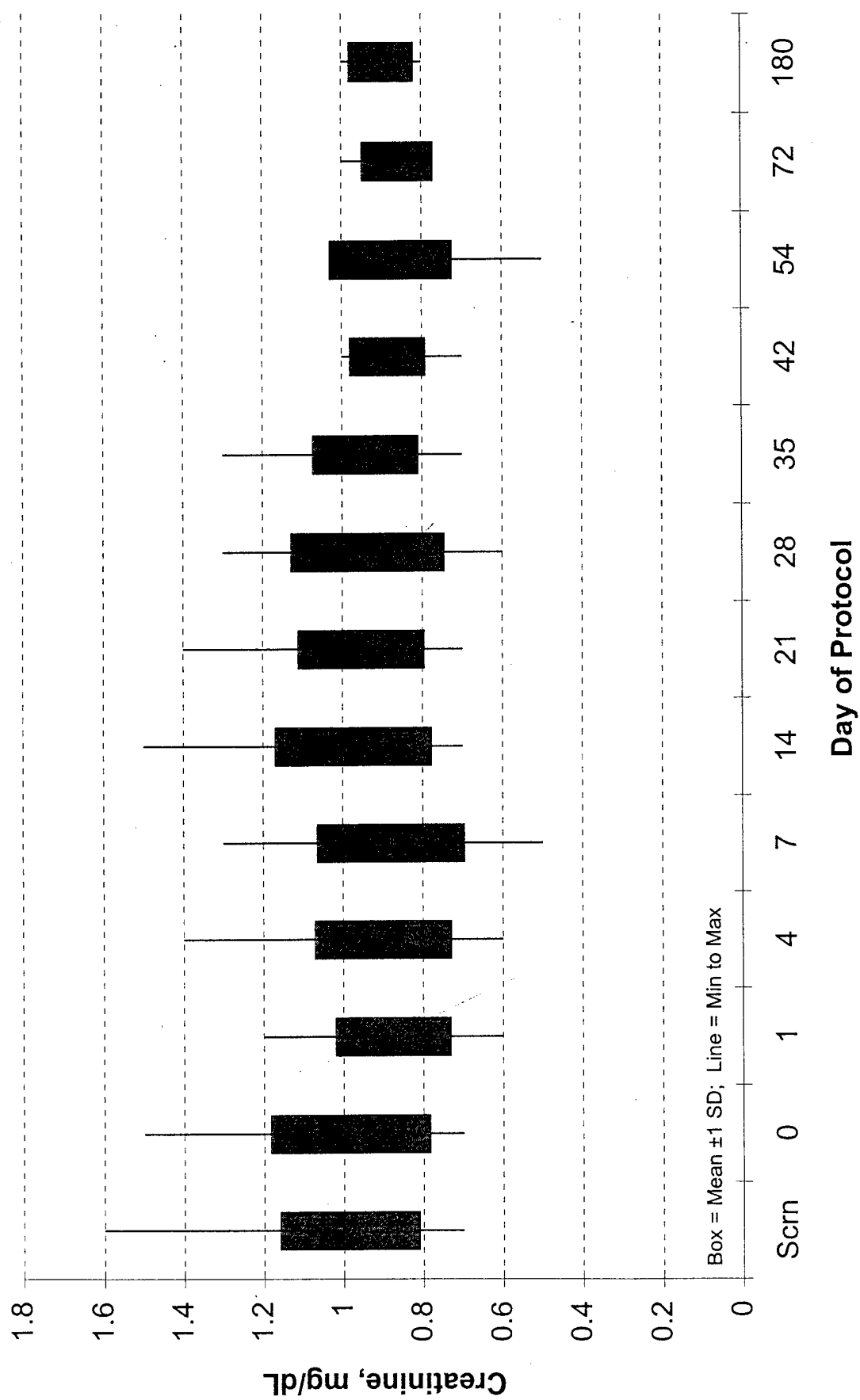
Units: mg/dL

Table 10j
Creatinine

Blank - Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|-------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 1.00 | 0.90 | 0.70 | 0.80 | 0.90 | 1.10 | 0.90 | 0.80 | 0.90 | 0.90 | 0.80 | 0.80 | 1.00 |
| 02 | 1.60 | 1.40 | 1.20 | 1.40 | 1.30 | 1.50 | 1.40 | 1.30 | 1.30 | | | | |
| 03 | 0.80 | 0.80 | 1.00 | 0.80 | 0.70 | 0.80 | | 0.80 | 0.70 | 0.80 | 0.80 | 0.80 | 0.80 |
| 04 | 1.10 | 1.00 | 0.80 | 0.70 | 0.70 | 0.70 | | 0.80 | 0.80 | | | | |
| 05 | 1.00 | | 1.00 | 0.90 | 1.10 | 1.30 | 1.10 | 1.20 | | | | | |
| 06 | 0.90 | 0.90 | 0.80 | 0.80 | 0.80 | 0.70 | 0.90 | 0.80 | 0.90 | 0.80 | 0.80 | 0.80 | 0.90 |
| 07 | 0.80 | | 0.60 | 0.60 | 0.50 | 0.80 | 0.80 | 0.60 | 0.80 | 1.00 | 0.70 | | |
| 08 | 1.00 | 0.90 | 0.80 | 0.90 | 0.70 | | | | | | | | |
| 09 | 1.00 | 0.90 | 0.80 | 0.90 | 0.90 | 0.90 | 0.90 | 1.00 | 0.90 | 0.90 | 0.90 | | |
| 10 | 0.90 | 0.90 | 0.70 | 0.90 | 0.70 | 1.00 | 0.80 | 0.80 | 0.90 | 0.90 | 1.00 | | |
| 11 | 0.70 | 0.70 | 0.80 | 0.70 | 0.80 | 0.80 | 0.70 | 0.60 | | 0.70 | | | |
| 12 | 1.00 | 1.20 | | 1.10 | 1.00 | 1.00 | 1.10 | 1.10 | 1.00 | 1.00 | 1.00 | | |
| 13 | 0.90 | 1.00 | 0.90 | 0.80 | 0.90 | 1.00 | 1.00 | 0.90 | 0.90 | 1.00 | 1.00 | | |
| 14 | 1.00 | 1.00 | 0.80 | 0.90 | 1.10 | 1.10 | 1.00 | 1.00 | 0.90 | | | | |
| 15 | 1.00 | 0.90 | 1.00 | 1.00 | 1.10 | 1.00 | 0.90 | 1.10 | 1.00 | 0.90 | 1.00 | | 0.90 |
| 16 | 1.00 | 1.00 | 0.90 | 0.90 | 0.90 | 1.10 | 0.90 | 1.00 | 0.90 | 0.90 | 1.00 | | |
| 17 | | 1.50 | 1.10 | | | | | | | | | | |
| 18 | 1.00 | 1.00 | 1.00 | 1.10 | 0.90 | 0.90 | 1.00 | 1.00 | 1.10 | 1.00 | | | |
| 19 | 0.90 | 0.80 | 0.90 | 0.90 | 0.80 | 1.00 | 1.00 | 0.90 | 1.00 | | 0.50 | | |
| 20 | 1.00 | 0.90 | 0.90 | 0.90 | 0.80 | 0.90 | 0.80 | 0.90 | 1.00 | 0.80 | 0.90 | 0.90 | |
| 21 | 1.10 | | 0.80 | 1.00 | 1.00 | 0.90 | 1.00 | 1.20 | 1.00 | 0.80 | 1.00 | 1.00 | |
| Summary: | Creatinine, mg/dL | | | | | | | | | | | | |
| Average | 0.99 | 0.98 | 0.88 | 0.90 | 0.88 | 0.97 | 0.95 | 0.94 | 0.94 | 0.89 | 0.88 | 0.86 | 0.90 |
| Std Dev | 0.18 | 0.20 | 0.14 | 0.17 | 0.19 | 0.20 | 0.16 | 0.19 | 0.13 | 0.09 | 0.15 | 0.09 | 0.08 |
| Max | 1.60 | 1.50 | 1.20 | 1.40 | 1.30 | 1.50 | 1.40 | 1.30 | 1.30 | 1.00 | 1.00 | 1.00 | 1.00 |
| Min | 0.70 | 0.70 | 0.60 | 0.60 | 0.50 | 0.70 | 0.70 | 0.60 | 0.70 | 0.70 | 0.50 | 0.80 | 0.80 |

Figure 37: SD & Range Charts for Creatinine, mg/dL



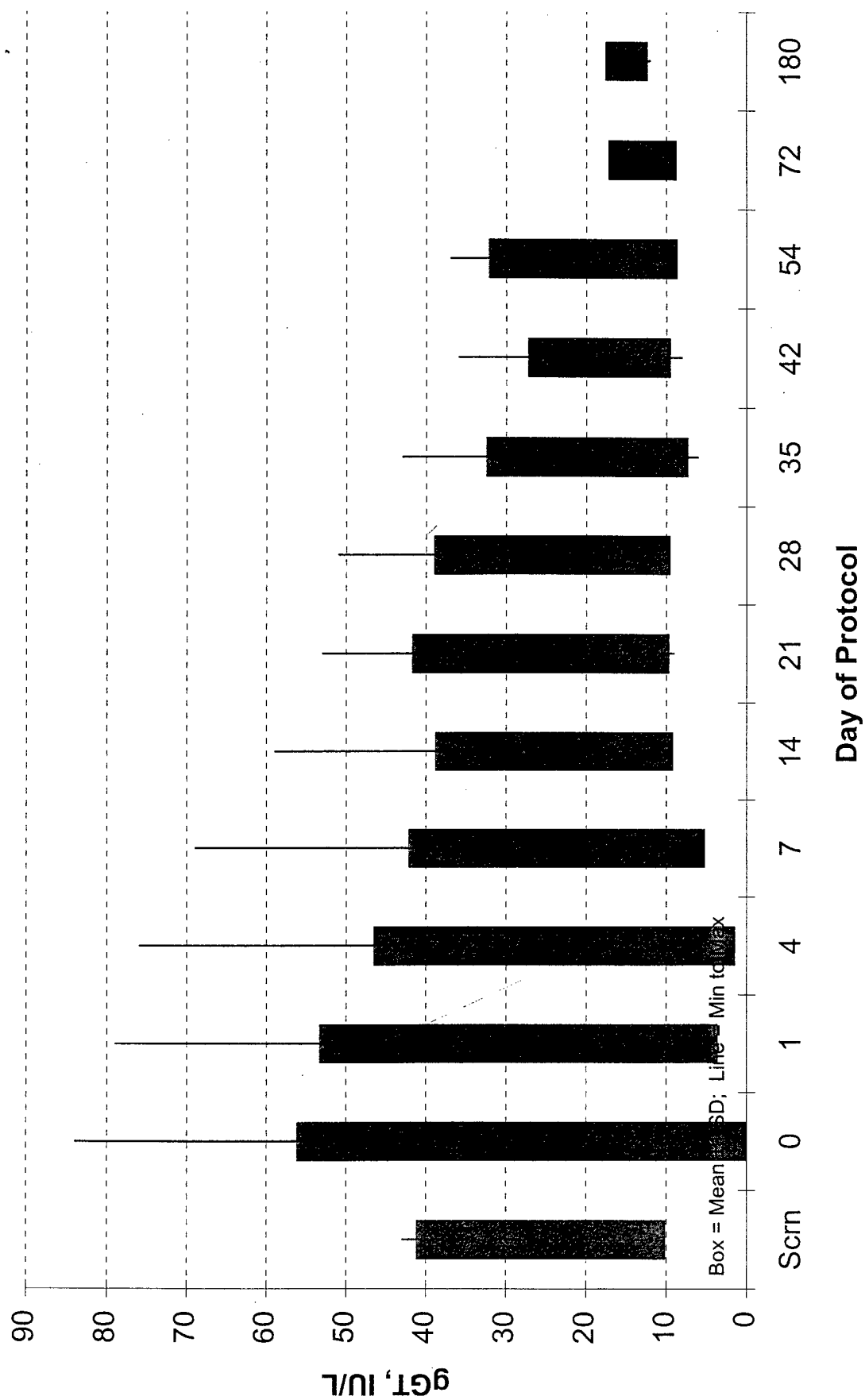
Blank = Not Obtained

Table 10k
gGT

Units: IU/L

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|-----------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | | | | | | | | | | | | | 16 |
| 02 | | | | | | | | | | | | | |
| 03 | | | | | | | | | | | | | 17 |
| 04 | | | | | | | | | | | | | |
| 05 | | | | | | | | | | | | | |
| 06 | | | | | | | | | | | | | |
| 07 | | | | | | | | | | | | | 12 |
| 08 | | | | | | | | | | | | | |
| 09 | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | |
| 13 | 13 | 13 | 9 | 10 | 11 | 12 | 13 | 12 | 10 | 9 | 11 | 10 | 12 |
| 14 | 43 | 84 | 79 | 76 | 69 | 59 | 53 | 47 | 43 | | | | |
| 15 | 21 | 19 | 17 | 17 | 15 | 11 | 15 | 12 | 20 | 16 | 18 | | |
| 16 | | 31 | 30 | 29 | 26 | 35 | 48 | 51 | 42 | 36 | 35 | | |
| 17 | | | 60 | | | | | | | | | | |
| 18 | | | 26 | | | | | | | | | | |
| 19 | | 7 | 11 | 11 | 12 | 10 | 9 | 11 | 13 | 26 | 37 | | |
| 20 | | 5 | 8 | 6 | 9 | 10 | 10 | 12 | 9 | 8 | 9 | | |
| 21 | | | 16 | 15 | 16 | 22 | 15 | 14 | 17 | 13 | 16 | 16 | |
| Summary: | gGT, IU/L | | | | | | | | | | | | |
| Average | 26 | 27 | 28 | 24 | 24 | 24 | 26 | 24 | 20 | 18 | 20 | 13 | 15 |
| Std Dev | 16 | 30 | 25 | 23 | 19 | 15 | 16 | 15 | 13 | 09 | 12 | 04 | 03 |
| Max | 43 | 84 | 79 | 76 | 69 | 59 | 53 | 51 | 43 | 36 | 37 | 16 | 17 |
| Min | 13 | 05 | 08 | 06 | 09 | 10 | 09 | 11 | 06 | 08 | 09 | 10 | 12 |

Figure 38: SD & Range Charts for gGT, IU/L



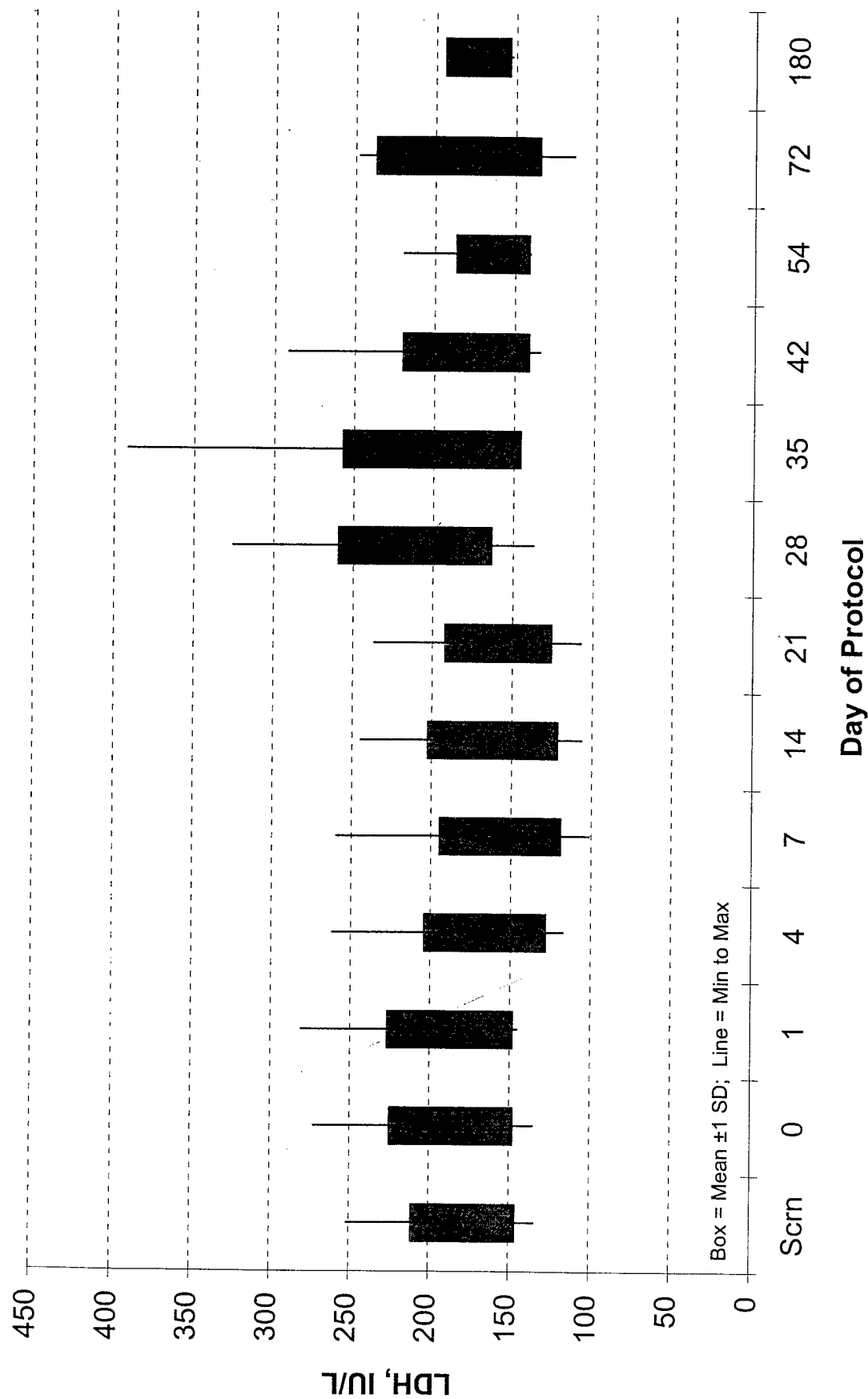
Units: IU/L

Table 10L
LDH

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|-----------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 158 | 158 | 152 | 138 | 130 | 153 | 161 | 163 | 161 | 160 | 140 | 113 | 152 |
| 02 | 165 | 180 | 208 | 155 | 140 | 175 | 198 | 196 | 195 | | | | |
| 03 | 185 | 176 | 222 | 219 | 170 | 231 | | 194 | 165 | 292 | 161 | 220 | 191 |
| 04 | 183 | 176 | 200 | 177 | 157 | 146 | | 268 | 194 | 218 | | | |
| 05 | 153 | | 189 | 126 | 126 | 120 | 130 | 155 | | | | | |
| 06 | 134 | 163 | 155 | 152 | 128 | 126 | 133 | 195 | 147 | 170 | 151 | 177 | 161 |
| 07 | 243 | | 252 | 186 | 260 | 181 | 237 | 262 | 392 | 226 | 220 | | |
| 08 | 179 | 158 | 196 | 181 | 171 | | | | | | | | |
| 09 | 138 | 135 | 192 | 185 | 191 | 156 | 196 | 261 | 211 | 160 | 149 | | |
| 10 | 171 | 169 | 154 | 196 | 177 | 156 | 196 | 261 | 211 | 160 | 149 | | |
| 11 | 191 | 178 | 168 | | 152 | 132 | 170 | 204 | | 147 | | | |
| 12 | 208 | 259 | | 213 | 218 | 208 | 164 | 184 | 185 | 181 | 157 | | |
| 13 | 156 | 168 | 186 | 117 | 170 | 106 | 120 | 137 | 169 | 176 | 148 | | |
| 14 | 160 | 189 | 258 | 131 | 126 | 129 | 155 | 202 | 257 | | | | |
| 15 | 188 | 166 | 145 | 127 | 166 | 245 | 128 | | 175 | 147 | 145 | | 192 |
| 16 | 153 | 157 | 152 | 130 | 119 | 127 | 146 | 194 | 197 | 165 | 149 | | |
| 17 | | 231 | 164 | | | | | | | | | | |
| 18 | 230 | 173 | 159 | 147 | 101 | 123 | 107 | 233 | 170 | 134 | 178 | | |
| 19 | 161 | 247 | 161 | 144 | 118 | 148 | 154 | 162 | 170 | | 164 | | |
| 20 | 252 | 273 | 281 | 262 | 184 | 207 | 171 | 326 | 222 | 195 | 188 | 248 | |
| 21 | 163 | | 154 | 168 | 134 | 209 | 136 | 209 | 201 | 175 | 196 | 171 | |
| Summary: | LDH, IU/L | | | | | | | | | | | | |
| Average | 179 | 186 | 187 | 166 | 157 | 162 | 159 | 211 | 201 | 180 | 164 | 186 | 174 |
| Std Dev | 33 | 39 | 40 | 38 | 38 | 41 | 34 | 48 | 56 | 40 | 23 | 52 | 21 |
| Max | 252 | 273 | 281 | 262 | 260 | 245 | 237 | 326 | 392 | 292 | 220 | 248 | 192 |
| Min | 134 | 135 | 145 | 117 | 101 | 106 | 107 | 137 | 147 | 134 | 140 | 113 | 152 |

Figure 39: SD & Range Charts for LDH, IU/L



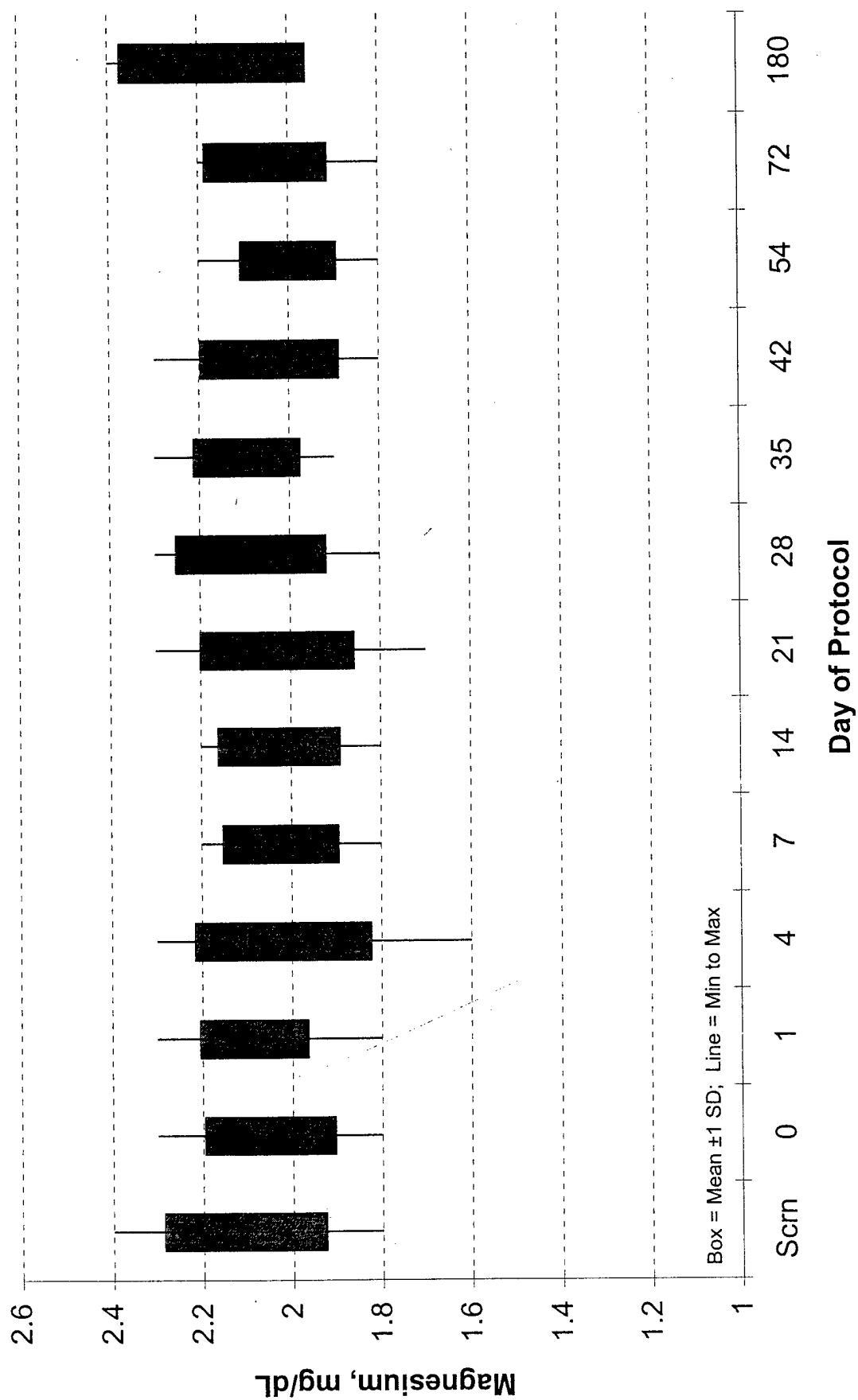
Units: mg/dL

Table 10m
Magnesium

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | 2.0 | 2.0 | 2.1 | 2.2 | | 1.9 | 2.1 | 2.0 | 2.0 | 2.2 | 2.1 | 2.1 | 2.1 |
| 02 | 2.3 | 1.9 | | 1.6 | | 1.8 | 2.0 | 1.8 | 2.1 | | | | |
| 03 | 2.0 | 1.9 | 2.0 | 1.7 | | 1.9 | | 2.2 | 1.9 | 2.1 | 2.0 | 2.0 | 2.4 |
| 04 | 2.3 | | 2.1 | 1.9 | 1.9 | 1.9 | | | 2.0 | 2.2 | | | |
| 05 | 1.9 | | 1.9 | | 1.9 | 1.9 | 1.9 | | | | | | |
| 06 | 1.9 | 1.9 | 2.0 | 2.0 | 2.1 | 1.9 | 2.0 | 2.0 | 1.9 | 2.1 | 2.1 | 2.1 | 2.0 |
| 07 | 2.2 | 2.1 | 2.3 | | 2.1 | 2.2 | 2.3 | 2.3 | 2.2 | | 2.0 | | |
| 08 | 2.1 | 2.0 | 2.2 | | 2.2 | | | | | | | | |
| 09 | 2.1 | 2.0 | 2.1 | | 2.1 | 2.1 | 2.2 | | 2.2 | 2.3 | 1.9 | | |
| 10 | 1.9 | 1.8 | 1.8 | 1.8 | 1.8 | 2.2 | 1.7 | 1.8 | 2.0 | 2.0 | | 1.8 | |
| 11 | 2.4 | 2.0 | 2.0 | 2.3 | 2.2 | 2.2 | 2.1 | | 2.0 | | | | |
| 12 | 2.2 | 2.2 | | 2.0 | 2.1 | 2.1 | 2.1 | 2.0 | 2.1 | 2.0 | 1.9 | | |
| 13 | 2.1 | 2.2 | 2.1 | 2.1 | 2.1 | 2.1 | 2.1 | 2.2 | 2.1 | 2.2 | 2.0 | | |
| 14 | 2.4 | 2.2 | 2.2 | 2.3 | 2.2 | 2.2 | 2.2 | 2.3 | 2.3 | | | | |
| 15 | | 2.0 | 2.1 | 2.1 | 1.9 | 2.1 | 1.8 | 2.1 | 2.1 | 1.8 | 1.9 | | |
| 16 | 2.2 | 2.1 | 2.1 | 2.0 | 1.9 | 2.0 | 2.0 | 2.2 | 2.2 | 1.9 | 2.0 | | |
| 17 | | 2.3 | 2.2 | | | | | | | | | | |
| 18 | | 1.9 | 2.0 | 2.0 | 1.9 | 1.9 | 2.1 | 2.1 | 2.1 | 1.9 | 2.1 | | |
| 19 | | 2.3 | 2.2 | 2.2 | 2.1 | 2.2 | 2.2 | 2.3 | 2.3 | 2.1 | 2.2 | | |
| 20 | 1.8 | 2.1 | 2.2 | 2.1 | 1.9 | 1.9 | 1.7 | 2.1 | | 1.8 | 1.8 | 2.1 | |
| 21 | 2.0 | | 2.0 | 2.0 | 2.0 | 2.0 | 2.0 | 1.9 | 2.1 | 2.0 | 2.0 | 2.2 | |
| Summary: | Magnesium, mg/dL | | | | | | | | | | | | |
| Average | 2.1 | 2.1 | 2.1 | 2.0 | 2.0 | 2.0 | 2.0 | 2.1 | 2.1 | 2.0 | 2.0 | 2.1 | 2.2 |
| Std Dev | 0.2 | 0.1 | 0.1 | 0.2 | 0.1 | 0.1 | 0.2 | 0.2 | 0.1 | 0.2 | 0.1 | 0.1 | 0.2 |
| Max | 2.4 | 2.3 | 2.3 | 2.3 | 2.2 | 2.2 | 2.3 | 2.3 | 2.3 | 2.3 | 2.2 | 2.2 | 2.4 |
| Min | 1.8 | 1.8 | 1.8 | 1.6 | 1.8 | 1.8 | 1.7 | 1.8 | 1.9 | 1.8 | 1.8 | 1.8 | 2.0 |

Figure 40: SD & Range Charts for Magnesium, mg/dL



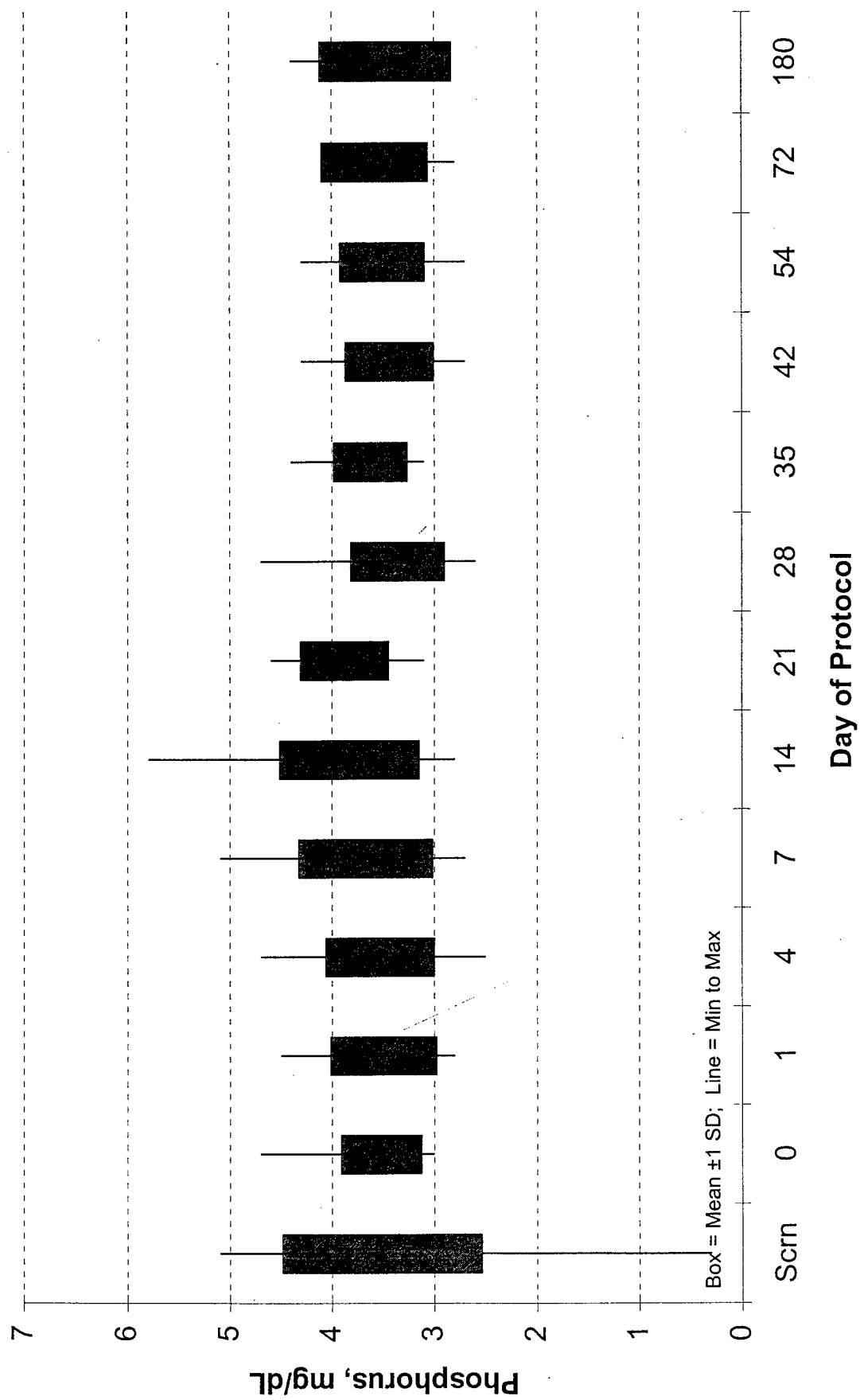
Units: mg/dL

Table 10n
Phosphorus

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|-------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 4.0 | 3.3 | 2.9 | 4.2 | 4.7 | 3.7 | 3.6 | 3.4 | 4.0 | 4.3 | 3.8 | 4.0 | 3.3 |
| 02 | 4.7 | 3.9 | 4.0 | 3.9 | 4.1 | 5.8 | 4.6 | 4.7 | 4.0 | | | | |
| 03 | 2.6 | 3.3 | 2.9 | 3.0 | 3.1 | 3.2 | 3.5 | 3.6 | 3.4 | 3.4 | 2.7 | 2.8 | 2.9 |
| 04 | 5.1 | 4.7 | 3.2 | 3.5 | 3.4 | 4.1 | | 3.0 | 3.8 | | | | |
| 05 | 3.1 | | 2.8 | 2.5 | 3.8 | 3.4 | 4.1 | 2.9 | | | | | |
| 06 | 3.9 | 3.9 | 3.2 | 3.5 | 3.6 | 3.7 | 3.9 | 3.5 | 3.6 | 3.3 | 3.1 | 3.6 | 3.3 |
| 07 | 3.0 | | 3.1 | 3.1 | 3.3 | 3.7 | 4.4 | 3.5 | 3.1 | | | | |
| 08 | 3.5 | 3.4 | 4.3 | 4.3 | 5.1 | 4.4 | | | | | | | |
| 09 | 4.1 | 3.5 | 4.3 | 3.6 | 4.3 | 3.4 | 3.7 | 3.1 | 3.4 | 3.2 | 3.8 | | |
| 10 | 3.3 | 3.3 | 3.5 | 3.3 | 3.3 | 3.0 | 3.1 | 3.2 | 3.3 | 3.2 | 3.6 | | |
| 11 | 2.9 | 3.0 | 3.1 | 2.9 | 2.7 | 2.8 | 3.5 | 2.6 | | 2.7 | | | |
| 12 | 3.0 | 3.2 | | 3.0 | 3.7 | 3.4 | 3.6 | 3.9 | 3.7 | 3.3 | 3.5 | | |
| 13 | 3.7 | 3.4 | 3.9 | 3.7 | 3.4 | 3.9 | 4.4 | 3.7 | 3.3 | 4.0 | 4.3 | | |
| 14 | 4.5 | 4.0 | 3.5 | 3.6 | 3.5 | 4.1 | | 3.4 | 3.6 | | | | |
| 15 | 3.6 | 3.4 | 4.5 | 4.7 | 4.7 | 4.7 | 3.7 | 3.4 | 3.8 | 3.8 | 3.1 | | 4.4 |
| 16 | 0.3 | 3.3 | 3.1 | 3.2 | 3.0 | 3.0 | 3.2 | 2.9 | 3.2 | 3.2 | 3.5 | | |
| 17 | | 3.4 | 4.1 | | | | | | | | | | |
| 18 | 3.6 | 3.7 | 3.0 | 3.4 | 2.8 | 3.8 | 4.1 | 3.0 | 4.1 | 3.2 | 3.8 | | |
| 19 | 3.8 | 3.4 | 3.5 | 3.8 | 3.2 | 4.0 | 4.2 | 3.6 | 3.7 | | 3.1 | | |
| 20 | 3.6 | 3.2 | 3.4 | 3.3 | 3.5 | 4.1 | 4.0 | 3.0 | 3.2 | 3.2 | 3.6 | 3.4 | |
| 21 | 3.9 | | 3.6 | 4.1 | 4.2 | 4.4 | 4.3 | 3.4 | 4.4 | 3.9 | 3.7 | 4.1 | |
| Summary: | Phosphorus, mg/dL | | | | | | | | | | | | |
| Average | 3.5 | 3.5 | 3.5 | 3.5 | 3.7 | 3.8 | 3.9 | 3.4 | 3.6 | 3.4 | 3.5 | 3.6 | 3.5 |
| Std Dev | 1.0 | 0.4 | 0.5 | 0.5 | 0.7 | 0.7 | 0.4 | 0.5 | 0.4 | 0.4 | 0.4 | 0.5 | 0.6 |
| Max | 5.1 | 4.7 | 4.5 | 4.7 | 5.1 | 5.8 | 4.6 | 4.7 | 4.4 | 4.3 | 4.3 | 4.1 | 4.4 |
| Min | 0.3 | 3.0 | 2.8 | 2.5 | 2.7 | 2.8 | 3.1 | 2.6 | 3.1 | 2.7 | 2.7 | 2.8 | 2.9 |

Figure 41: SD & Range Charts for Phosphorus, mg/dL



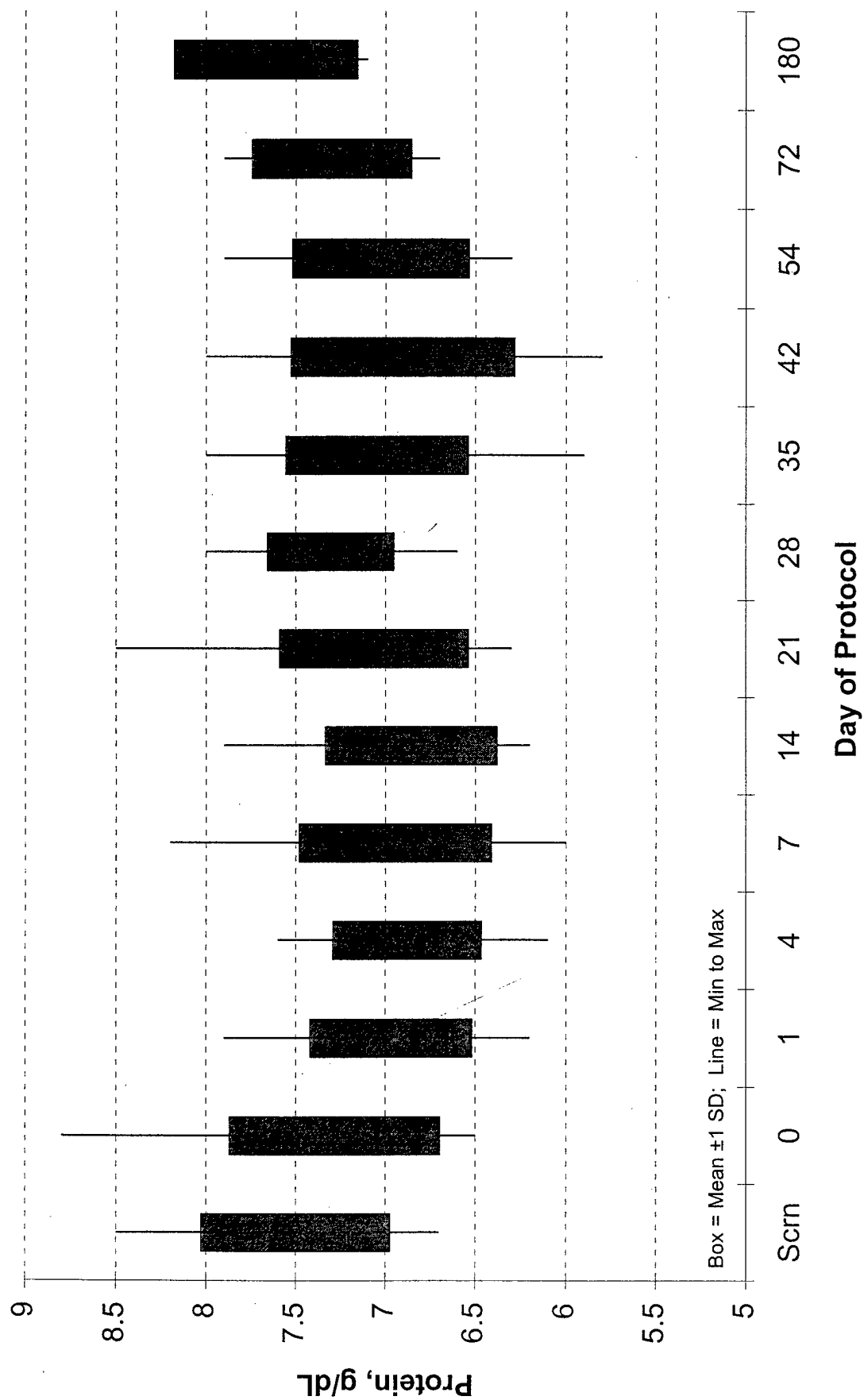
g/dL

Table 10o
Protein

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|------------------------|------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | 8.50 | 8.80 | 7.90 | 7.60 | 7.40 | 7.90 | 8.50 | 7.30 | 7.10 | 8.00 | 7.70 | 7.90 | 8.10 |
| 02 | 7.30 | 7.40 | 7.00 | 6.80 | 6.90 | 7.60 | 7.20 | 7.30 | 6.90 | | | | |
| 03 | 7.20 | 6.60 | 7.60 | 6.10 | 6.00 | 6.40 | | 7.40 | 6.10 | 6.50 | 6.60 | 6.70 | 7.10 |
| 04 | 7.30 | 6.60 | 7.20 | 6.90 | 6.90 | 6.60 | | 7.60 | 7.20 | 7.60 | | | |
| 05 | 6.70 | | 6.40 | 6.10 | 6.10 | 6.20 | 6.50 | 7.60 | | | | | |
| 06 | 7.70 | 7.40 | 7.20 | 6.90 | 7.00 | 6.60 | 7.60 | 7.70 | 8.00 | 7.40 | 7.40 | 7.30 | 7.80 |
| 07 | 7.80 | | 6.90 | 6.70 | 7.70 | 7.30 | 7.50 | 7.60 | 7.60 | 7.00 | 7.10 | | |
| 08 | 8.20 | 7.50 | 7.40 | 7.10 | 7.50 | | | | | | | | |
| 09 | 7.10 | 6.50 | 6.40 | 6.50 | 6.80 | 6.60 | 7.00 | 6.70 | 5.90 | 6.70 | 6.80 | | |
| 10 | 7.50 | 7.20 | 7.30 | 7.00 | 7.00 | 7.40 | 6.60 | 7.40 | 7.20 | 6.80 | 7.60 | | |
| 11 | 7.90 | 7.80 | 7.50 | | 8.20 | 6.70 | 7.40 | 7.20 | | 6.90 | | | |
| 12 | 8.50 | 7.50 | | 7.40 | 7.20 | 7.60 | 7.50 | 7.50 | 7.70 | 7.20 | 7.20 | | |
| 13 | 7.50 | 7.50 | 6.70 | 6.30 | 6.70 | 6.60 | 7.10 | 6.90 | 7.00 | 7.90 | 7.00 | | |
| 14 | 7.20 | | | 7.20 | 7.50 | 7.10 | 7.10 | 7.10 | 6.90 | | | | |
| 15 | 8.20 | 7.20 | 6.50 | 6.90 | 6.70 | 6.50 | 6.80 | | 7.40 | 5.80 | 6.30 | | |
| 16 | 7.10 | 7.00 | 6.60 | 6.90 | 6.50 | 6.50 | 6.70 | 7.00 | 6.90 | 6.20 | 7.00 | | |
| 17 | | 8.10 | 7.10 | | | | | | | | | | |
| 18 | 7.20 | 7.00 | 6.80 | 7.00 | 6.70 | 6.60 | 6.70 | 7.20 | 7.00 | 6.60 | 7.90 | | |
| 19 | 6.80 | 6.70 | 6.20 | 6.80 | 6.30 | 6.50 | 6.30 | 6.60 | 6.80 | | 6.40 | | |
| 20 | 7.10 | 7.00 | 6.90 | 7.50 | 6.80 | 6.70 | 6.70 | 8.00 | 7.00 | 6.30 | 6.50 | 7.50 | |
| 21 | 7.20 | | 6.80 | 7.00 | 7.00 | 6.90 | 6.90 | 7.40 | 7.10 | 6.70 | 6.90 | 7.10 | |
| Summary: Protein, g/dL | | | | | | | | | | | | | |
| Average | 7.50 | 7.28 | 6.97 | 6.88 | 6.95 | 6.86 | 7.06 | 7.31 | 7.05 | 6.91 | 7.03 | 7.30 | 7.67 |
| Std Dev | 0.53 | 0.59 | 0.45 | 0.42 | 0.54 | 0.48 | 0.53 | 0.36 | 0.51 | 0.62 | 0.49 | 0.45 | 0.51 |
| Max | 8.50 | 8.80 | 7.90 | 7.60 | 8.20 | 7.90 | 8.50 | 8.00 | 8.00 | 8.00 | 7.90 | 7.90 | 8.10 |
| Min | 6.70 | 6.50 | 6.20 | 6.10 | 6.00 | 6.20 | 6.30 | 6.60 | 5.90 | 5.80 | 6.30 | 6.70 | 7.10 |

Figure 42: SD & Range Charts for Protein, g/dL



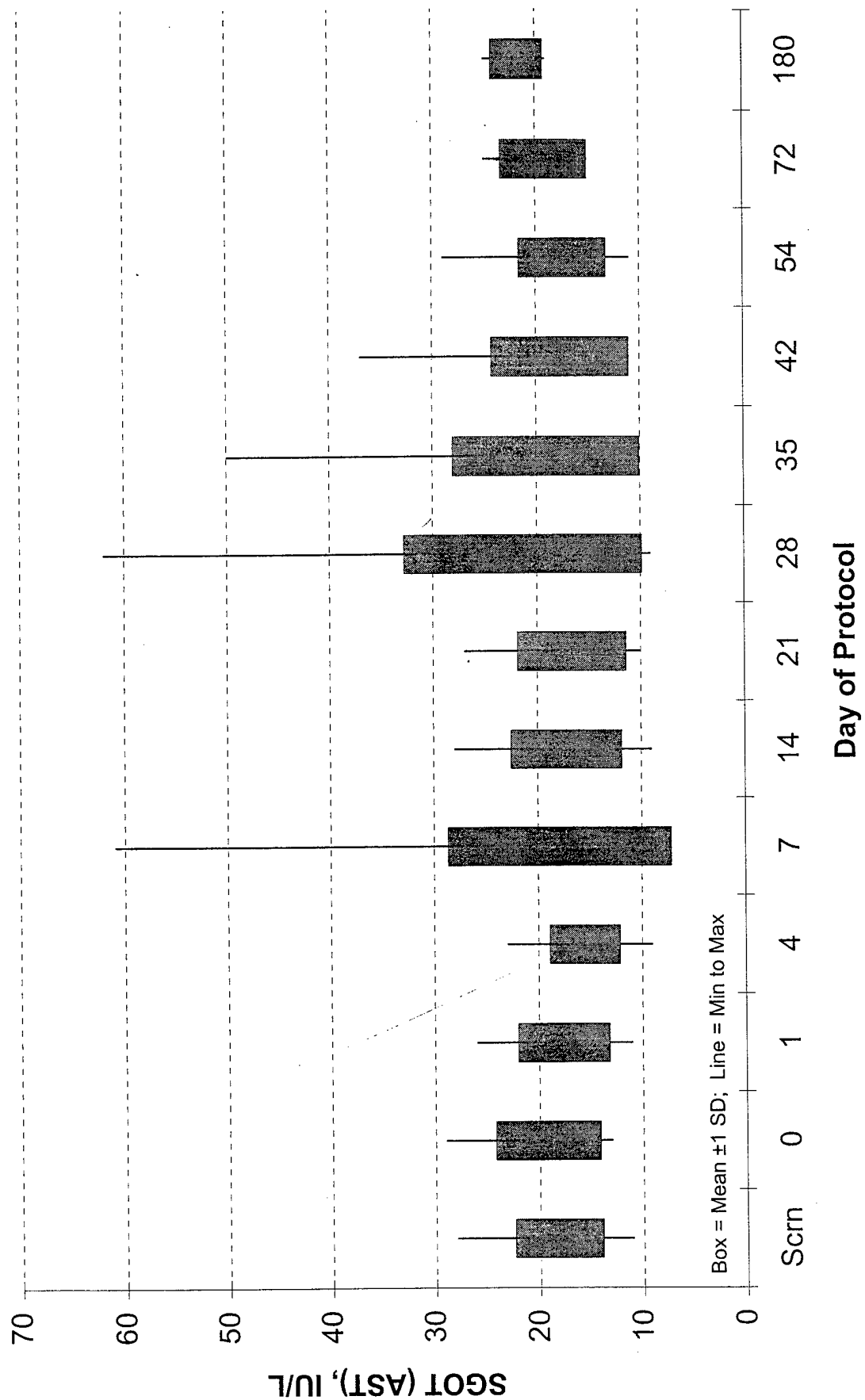
Blank = Not Obtained

Table 10p
SGOT (AST)

Units: IU/L

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 18 | 19 | 19 | 15 | 17 | 17 | 19 | 15 | 13 | 14 | 14 | 17 | 22 |
| 02 | 21 | 29 | 26 | 21 | 18 | 22 | 20 | 17 | 18 | | | | |
| 03 | 15 | 18 | 24 | 19 | 14 | 22 | | 22 | 16 | 37 | 16 | 25 | 21 |
| 04 | 18 | 17 | 17 | 15 | 18 | 17 | | 17 | 18 | 19 | | | |
| 05 | 11 | | 14 | 13 | 13 | 9 | 10 | 14 | | | | | |
| 06 | 16 | 16 | 15 | 14 | 19 | 16 | 22 | 23 | 19 | 16 | 18 | 15 | 19 |
| 07 | 20 | | 25 | 14 | 61 | 24 | 26 | 28 | 30 | 23 | 21 | | |
| 08 | 14 | 13 | 11 | 12 | 13 | | | | | | | | |
| 09 | 20 | 16 | 16 | 17 | 15 | 16 | 13 | 62 | 50 | 12 | 16 | | |
| 10 | 16 | 17 | 14 | 17 | 15 | 18 | 14 | 18 | 16 | 15 | 18 | | |
| 11 | 17 | 18 | 15 | | 14 | 10 | 16 | 16 | | 11 | | | |
| 12 | 25 | 27 | | 18 | 20 | 21 | 20 | 18 | 17 | 19 | 15 | | |
| 13 | 16 | 16 | 17 | 14 | 14 | 11 | 13 | 18 | 17 | 20 | 16 | | |
| 14 | 18 | 17 | 14 | 13 | 13 | 13 | 12 | 12 | 14 | | | | |
| 15 | 18 | 15 | 14 | 13 | 13 | 16 | 11 | | 16 | 13 | 11 | | 25 |
| 16 | 26 | 22 | 20 | 23 | 26 | 28 | 27 | 30 | 22 | 23 | 29 | | |
| 17 | | 26 | 23 | | | | | | | | | | |
| 18 | 28 | 28 | 22 | 13 | 16 | 24 | 19 | 19 | 13 | 18 | 17 | | |
| 19 | 15 | 13 | 12 | 9 | 8 | 10 | 10 | 9 | 11 | | 15 | | |
| 20 | 14 | 18 | 16 | 19 | 16 | 14 | 17 | 26 | 16 | 12 | 17 | 17 | |
| 21 | 17 | | 18 | 16 | 15 | 19 | 14 | 20 | 18 | 13 | 21 | 22 | |
| Summary: | SGOT (AST), IU/L | | | | | | | | | | | | |
| Average | 18 | 19 | 18 | 16 | 18 | 17 | 17 | 21 | 19 | 18 | 17 | 19 | 22 |
| Std Dev | 04 | 05 | 04 | 03 | 11 | 05 | 05 | 11 | 09 | 07 | 04 | 04 | 03 |
| Max | 28 | 29 | 26 | 23 | 61 | 28 | 27 | 62 | 50 | 37 | 29 | 25 | 25 |
| Min | 11 | 13 | 11 | 09 | 08 | 09 | 10 | 09 | 11 | 11 | 11 | 15 | 19 |

Figure 43: SD & Range Charts for SGOT (AST), IU/L



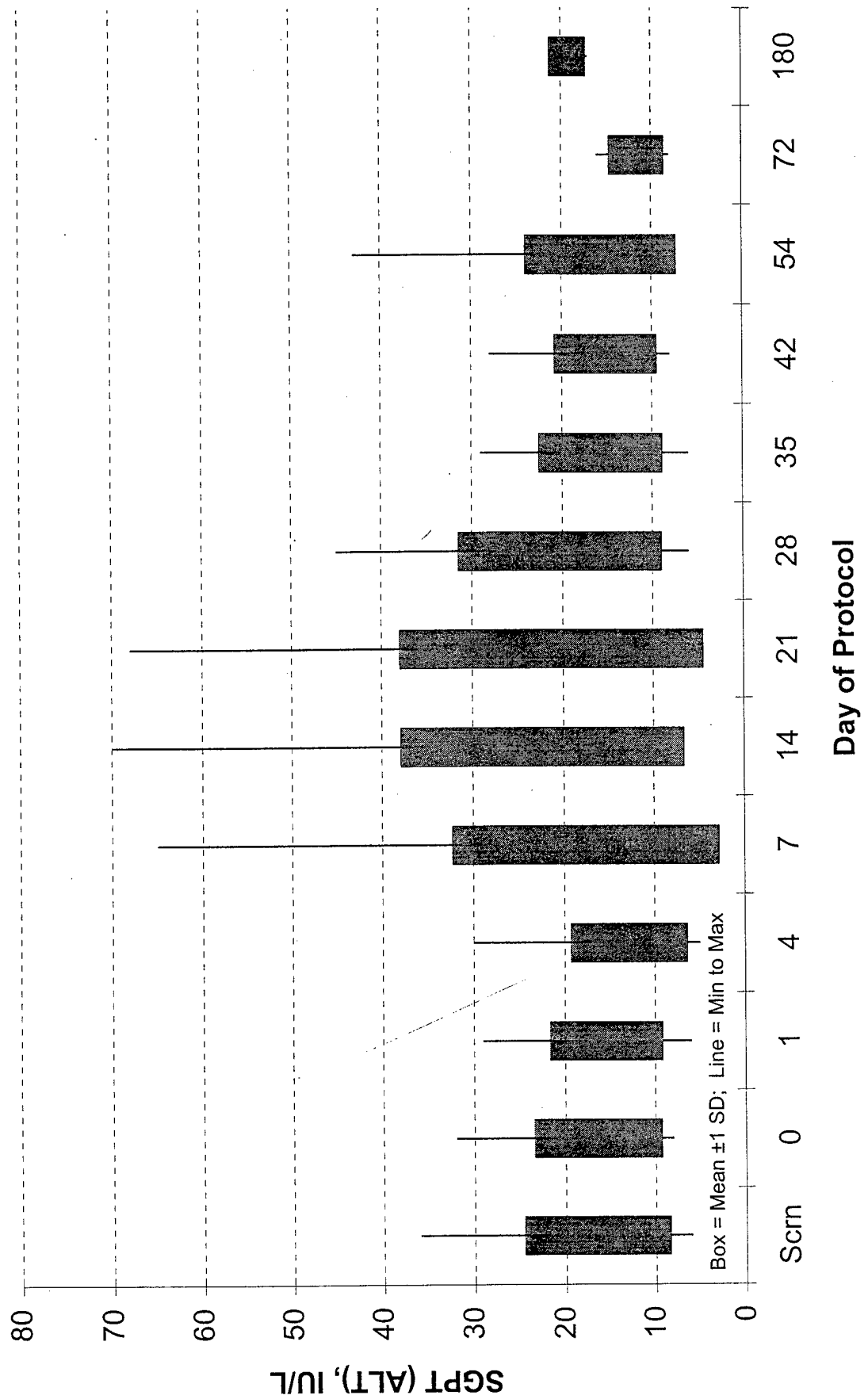
Units: IU/L

Table 10q
SGPT (ALT)

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------|------------------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 15 | 17 | 16 | 11 | 17 | 19 | 20 | 15 | 9 | 10 | 9 | 11 | 18 |
| 02 | 24 | 32 | 29 | 27 | 27 | 32 | 26 | 21 | 14 | | | | |
| 03 | 11 | 13 | 16 | 13 | 11 | 21 | | 13 | 15 | 24 | 15 | 16 | 17 |
| 04 | 16 | 20 | 21 | 20 | 30 | 34 | | 22 | 13 | 14 | | | |
| 05 | 6 | | 10 | 9 | 9 | 8 | 6 | 8 | | | | | |
| 06 | 16 | 15 | 14 | 11 | 18 | 20 | 25 | 29 | 18 | 10 | 15 | 8 | 21 |
| 07 | 13 | | 16 | 12 | 65 | 45 | 55 | 40 | 29 | 20 | 14 | | |
| 08 | 9 | 8 | 6 | 6 | 6 | | | | | | | | |
| 09 | 27 | 17 | 15 | 14 | 11 | 11 | 9 | 45 | 28 | 18 | 19 | | |
| 10 | 9 | 11 | 19 | 7 | 11 | 17 | 15 | 17 | 12 | 14 | 15 | | |
| 11 | 15 | 11 | 11 | | 6 | 9 | 11 | 9 | 15 | 8 | | | |
| 12 | 16 | 13 | | 13 | 14 | 20 | 19 | 17 | 9 | 13 | 13 | | |
| 13 | 6 | 8 | 7 | 5 | 4 | 9 | 6 | 6 | 6 | 10 | 10 | | |
| 14 | 32 | 20 | 17 | 13 | 15 | 13 | 14 | 16 | 12 | | | | |
| 15 | 16 | 13 | 11 | 8 | 11 | 12 | 13 | | 23 | 16 | 13 | | 21 |
| 16 | 36 | 27 | 25 | 30 | 46 | 70 | 68 | 36 | 28 | 28 | 43 | | |
| 17 | | 30 | 27 | | | | | | | | | | |
| 18 | 22 | 16 | 14 | 11 | 16 | 39 | 31 | 29 | 16 | 19 | 14 | | |
| 19 | 13 | 13 | 11 | 10 | 11 | 16 | 11 | 14 | 12 | | 12 | | |
| 20 | 11 | 10 | 10 | 10 | 11 | 12 | 15 | 10 | 13 | 10 | 9 | 10 | |
| 21 | 16 | | 13 | 14 | 12 | 16 | 17 | 17 | 11 | 13 | 18 | 13 | |
| Summary: | | SGPT (ALT), IU/L | | | | | | | | | | | |
| Average | 16 | 16 | 15 | 13 | 18 | 22 | 21 | 20 | 16 | 15 | 16 | 12 | 19 |
| Std Dev | 08 | 07 | 06 | 06 | 15 | 16 | 17 | 11 | 07 | 06 | 08 | 03 | 02 |
| Max | 36 | 32 | 29 | 30 | 65 | 70 | 68 | 45 | 29 | 28 | 43 | 16 | 21 |
| Min | 06 | 08 | 06 | 05 | 04 | 08 | 06 | 06 | 06 | 08 | 09 | 08 | 17 |

Figure 44: SD & Range Charts for SGPT (ALT), IU/L



Units: mg/dL

Table 10r
Uric Acid

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|------|------------------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 5.6 | 6.6 | 6.9 | 5.8 | 6.1 | 7.1 | 7.4 | 6.0 | 6.9 | 6.3 | 6.1 | 5.8 | 6.9 |
| 02 | 6.3 | 5.7 | 5.7 | 5.5 | 6.0 | 5.8 | 6.3 | 5.0 | 4.2 | | | | |
| 03 | 3.2 | 3.8 | 5.5 | 4.4 | 3.7 | 3.9 | | 4.8 | 3.8 | 4.5 | 3.7 | 4.3 | 4.7 |
| 04 | 5.2 | 5.1 | 5.1 | 5.5 | 5.2 | 5.0 | | 5.8 | 5.8 | 5.2 | | | |
| 05 | 5.8 | | 6.4 | 5.6 | 5.7 | 5.6 | 5.7 | 5.4 | | | | | |
| 06 | 4.8 | 4.5 | 4.7 | 4.0 | 4.8 | 4.4 | 4.6 | 4.5 | 4.3 | 5.2 | 5.3 | 4.4 | 5.0 |
| 07 | 6.3 | | 4.9 | 4.8 | 4.8 | 5.7 | 5.6 | 7.3 | 5.1 | 6.0 | 5.8 | | |
| 08 | 5.5 | 5.4 | 5.4 | 5.7 | 5.4 | | | | | | | | |
| 09 | 6.1 | 4.5 | 4.3 | 4.8 | 5.0 | 5.6 | 5.4 | 4.3 | 5.7 | 4.8 | 4.6 | | |
| 10 | 3.9 | 3.8 | 3.7 | 4.7 | 3.9 | 5.1 | 4.5 | 4.3 | 4.5 | 4.6 | 4.1 | | |
| 11 | 4.1 | 6.5 | 4.5 | 3.9 | 3.4 | 3.8 | 4.0 | 4.6 | | 3.9 | | | |
| 12 | 4.4 | 6.0 | | 5.2 | 5.0 | 5.2 | 5.2 | 5.6 | 5.4 | 4.8 | 5.2 | | |
| 13 | 4.6 | 4.8 | 4.8 | 4.8 | 4.1 | 4.7 | 5.0 | 4.9 | 4.2 | 4.7 | 4.8 | | |
| 14 | 5.3 | 6.1 | 6.0 | 6.9 | 6.6 | 7.1 | 6.6 | 6.7 | 5.7 | | | | 6.4 |
| 15 | 6.6 | 6.0 | 6.4 | 7.0 | 6.6 | 6.6 | 5.9 | 5.5 | 6.1 | 6.3 | 5.8 | | |
| 16 | 4.8 | 5.1 | 4.9 | 5.5 | 5.3 | 5.2 | 5.6 | 5.1 | 4.9 | 5.1 | 4.9 | | |
| 17 | | 8.1 | 7.3 | | | | | | | | | | |
| 18 | 5.4 | 6.1 | 5.6 | 5.1 | 5.5 | 5.8 | 6.1 | 6.7 | 5.8 | 4.7 | 4.8 | | |
| 19 | 6.6 | 6.5 | 6.4 | 6.9 | 6.4 | 6.8 | 6.5 | 5.9 | 6.7 | | 6.6 | | |
| 20 | 5.6 | 5.7 | 5.6 | 5.7 | 5.4 | 6.1 | 6.6 | 6.2 | 5.7 | 5.4 | 5.7 | 5.6 | |
| 21 | 5.7 | | 5.1 | 5.9 | 5.3 | 5.8 | 5.9 | 5.2 | 5.8 | 5.5 | 5.4 | 5.3 | |
| Summary: | | Uric Acid, mg/dL | | | | | | | | | | | |
| Average | 5.3 | 5.6 | 5.5 | 5.4 | 5.2 | 5.5 | 5.7 | 5.5 | 5.3 | 5.1 | 5.2 | 5.1 | 5.8 |
| Std Dev | 0.9 | 1.1 | 0.9 | 0.9 | 0.9 | 1.0 | 0.9 | 0.9 | 0.9 | 0.7 | 0.8 | 0.7 | 1.1 |
| Max | 6.6 | 8.1 | 7.3 | 7.0 | 6.6 | 7.1 | 7.4 | 7.3 | 6.9 | 6.3 | 6.6 | 5.8 | 6.9 |
| Min | 3.2 | 3.8 | 3.7 | 3.9 | 3.4 | 3.8 | 4.0 | 4.3 | 3.8 | 3.9 | 3.7 | 4.3 | 4.7 |

Figure 45: SD & Range Charts for Uric Acid, mg/dL

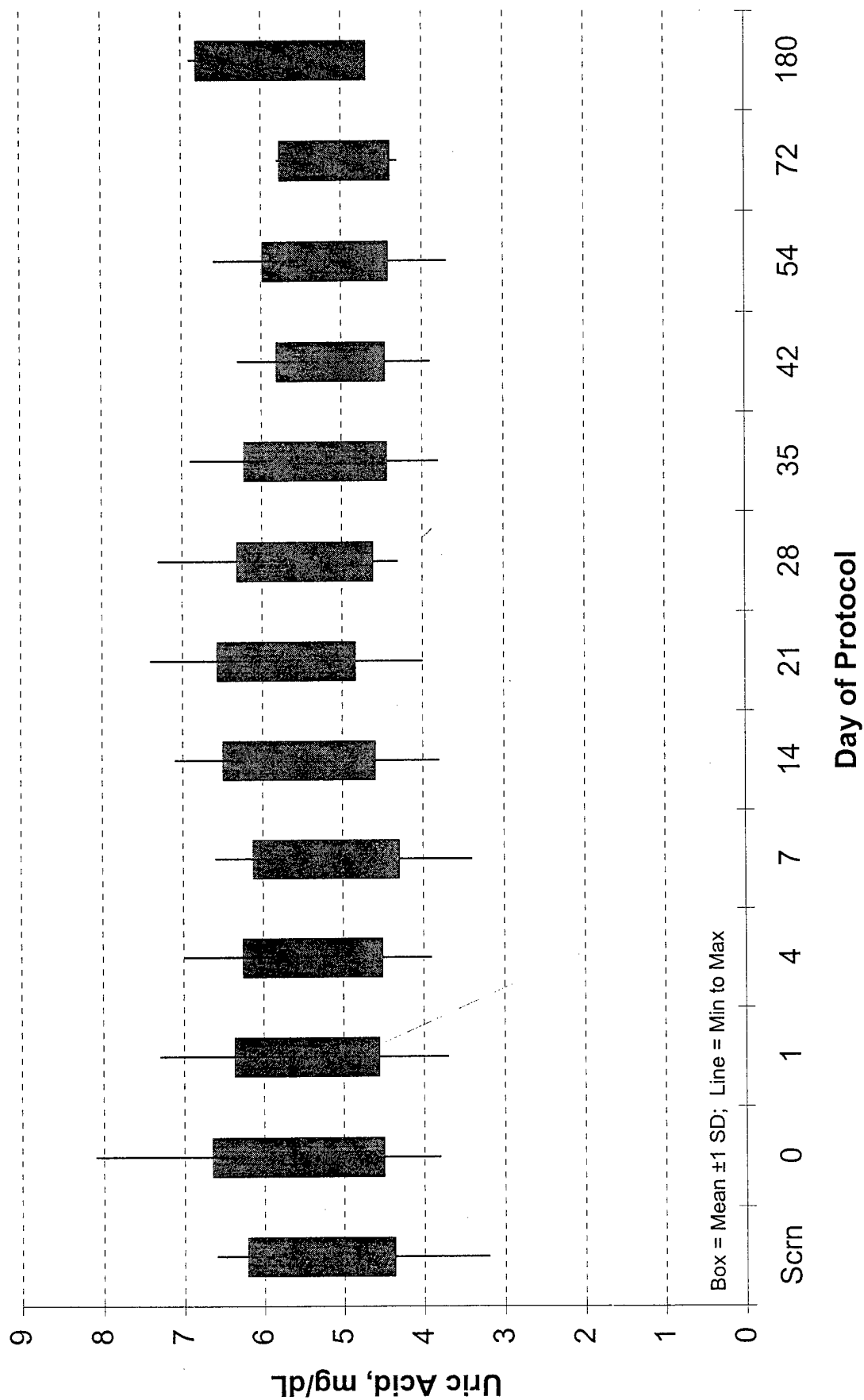


Table 11a
Urinalysis: Casts

per LPF

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|---------|------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | | | | | | | | | | | | | |
| 02 | | | | | | | | | | | | | |
| 03 | | | | | | | | | | | | | |
| 04 | | | | | | | | | | | | | |
| 05 | | | | | | | | | | | | | |
| 06 | | | | | | | | | | | | | |
| 07 | | | | | | | | | | | | | |
| 08 | | | | | | | | | | | | | |
| 09 | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | |
| 13 | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | |
| 17 | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | |
| 21 | | | | | | | | | | | | | |

Table 11b
Urinalysis: Occult Blood

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|---------|------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 01 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 02 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 03 | 4+ | - | 1+ | - | - | - | 4+ | 1+ | 1+ | - | - | 4+ | 4+ |
| 04 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 05 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 06 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 07 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 08 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 09 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 10 | - | - | 1+ | - | - | - | - | - | 4+ | - | - | - | - |
| 11 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | - | - | - | - | - | - | - | - | + | - | - | - | - |
| 13 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | - | - | - | - | - | - | 1+ | + | + | - | - | - | - |
| 15 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 18 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 19 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 20 | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 21 | - | - | - | - | - | - | - | - | - | - | - | - | - |

Table 11c
Urinalysis: RBC

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|--------------------|------|-------|-------|-------|-------|--------|--------|--------|--------|--------|--------|--------|---------|
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 18 | 1 | 1 | 0 | 3 |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 18 | | | | |
| 3 | 50 | 0 | 2 | 0 | 0 | 0 | 13 | 9 | 1 | 3 | 6 | 1 | 1 |
| 4 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 5 | 0 | | | | |
| 5 | 0 | 16 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | | | | |
| 6 | 1 | 15 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| 7 | 1 | 0 | 0 | 0 | 0 | 0 | | 1 | 0 | 0 | 0 | | |
| 8 | 0 | 0 | 0 | 0 | 0 | | | | | | | | |
| 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | | |
| 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | |
| 11 | 2 | 7 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | 0 | | |
| 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 0 | | |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | |
| 14 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | |
| 15 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 | 0 | | 0 |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | | |
| 17 | 0 | 0 | 0 | | | | | | | | | | |
| 18 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | |
| 21 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 3 | |
| Summary: Urine RBC | | | | | | | | | | | | | |
| Average | 2.7 | 2.0 | 0.1 | 0.1 | 0.1 | 0.1 | 0.9 | 1.0 | 2.4 | 0.4 | 0.5 | 0.8 | 1.3 |
| Std Dev | 10.9 | 4.8 | 0.4 | 0.4 | 0.2 | 0.5 | 3.1 | 2.3 | 5.7 | 0.8 | 1.6 | 1.3 | 1.3 |
| Max | 50 | 16 | 2 | 2 | 1 | 2 | 13 | 9 | 18 | 3 | 6 | 3 | 3 |
| Min | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Figure 46: SD & Range Charts for Urine RBC

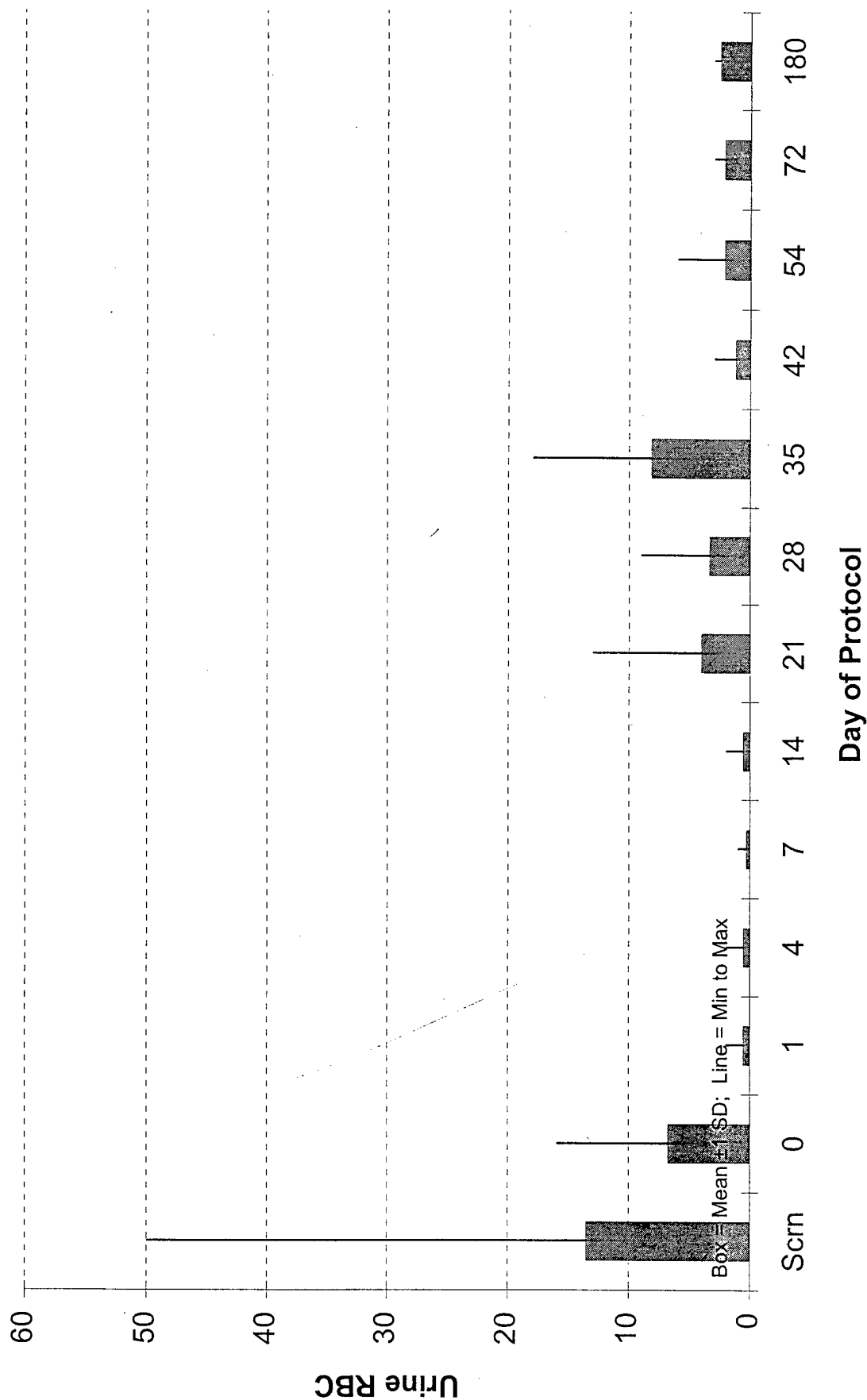


Table 11d
Urinalysis: WBC

Blank= Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|-----------------|------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 2 |
| 02 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | | | | |
| 03 | 0 | 0 | 40 | 0 | 1 | 0 | 0 | 11 | 15 | 3 | 2 | 0 | 0 |
| 04 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 3 | 0 | 0 | | | |
| 05 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | | | | |
| 06 | 1 | 2 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| 07 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | |
| 08 | 0 | 0 | 0 | 3 | 0 | | | | | | | | |
| 09 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 10 | 0 | 0 | 4 | 5 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | | |
| 11 | 4 | 19 | 0 | 1 | 2 | 0 | 0 | 1 | 0 | 0 | 0 | | |
| 12 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0 | | | |
| 13 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | |
| 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | | |
| 15 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | | |
| 16 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | | | |
| 17 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | |
| 18 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 19 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | 0 | 0 | 0 | | |
| 20 | 0 | 8 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 2 | | |
| 21 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | |
| Summary: | | | | | | | | | | | | | |
| Urine WBC | | | | | | | | | | | | | |
| Average | 0.4 | 1.6 | 2.1 | 0.5 | 0.2 | 0.1 | 0.3 | 1.1 | 1.3 | 0.2 | 0.3 | 0.4 | 0.7 |
| Std Dev | 0.9 | 4.4 | 8.7 | 1.2 | 0.5 | 0.2 | 0.6 | 2.5 | 3.5 | 0.8 | 0.8 | 0.9 | 1.2 |
| Max | 4 | 19 | 40 | 5 | 2 | 1 | 2 | 11 | 15 | 3 | 2 | 2 | 2 |
| Min | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Figure 47: SD & Range Charts for Urine WBC

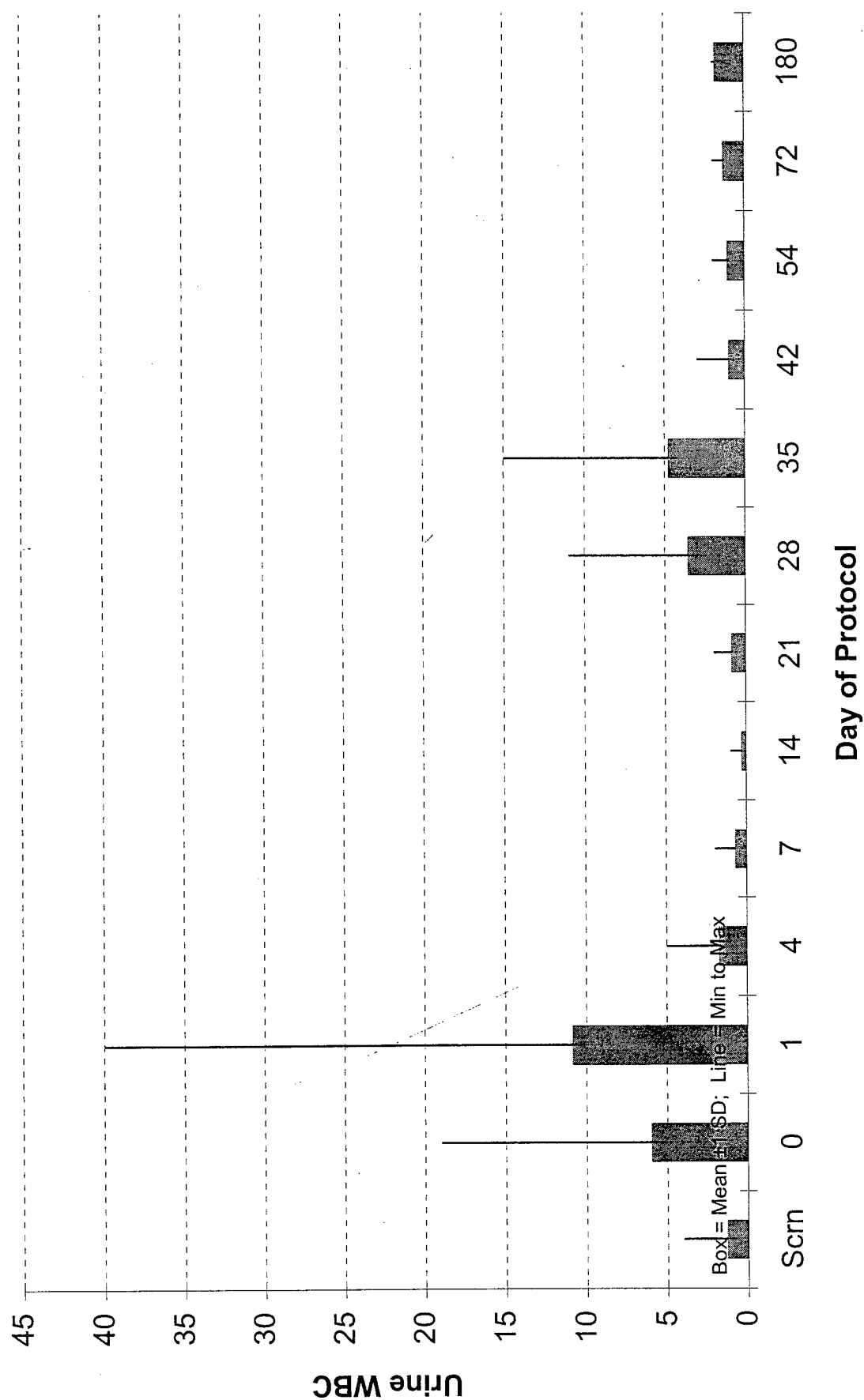


Table 11e
Urinalysis: Specific Gravity

Blank = Not Obtained

| Subject | Scrn | DAY 0 | DAY 1 | DAY 4 | DAY 7 | DAY 14 | DAY 21 | DAY 28 | DAY 35 | DAY 42 | DAY 54 | DAY 72 | DAY 180 |
|----------|-------------------------|----------|----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|
| 01 | 1.026 | 1.023 | 1.031 | 1.030 | 1.026 | 1.027 | | 1.029 | 1.029 | 1.022 | 1.032 | 1.031 | 1.018 |
| 02 | 1.026 | 1.015 | 1.018 | 1.022 | 1.025 | 1.021 | 1.019 | 1.025 | 1.015 | | | | |
| 03 | 1.009 | 1.019 | 1.016 | 1.007 | 1.019 | 1.005 | 1.005 | 1.019 | 1.022 | 1.022 | 1.019 | 1.019 | 1.021 |
| 04 | 1.027 | 1.016 | 1.018 | 1.026 | 1.026 | 1.014 | 1.027 | 1.030 | 1.028 | | | | |
| 05 | 1.015 | 1.008 | 1.016 | 1.025 | 1.019 | 1.026 | 1.023 | 1.009 | 1.013 | | | | |
| 06 | 1.028 | 1.012 | 1.026 | 1.026 | 1.022 | 1.023 | 1.025 | 1.027 | 1.027 | 1.021 | 1.025 | 1.026 | 1.020 |
| 07 | 1.034 | 1.022 | 1.023 | 1.008 | 1.009 | 1.011 | | 1.027 | 1.029 | 1.028 | 1.030 | | |
| 08 | 1.033 | 1.021 | 1.015 | 1.029 | 1.029 | | | | | | | | |
| 09 | 1.029 | 1.007 | 1.026 | 1.029 | 1.020 | 1.019 | 1.020 | 1.016 | 1.028 | 1.022 | | | |
| 10 | 1.026 | 1.015 | 1.008 | 1.018 | 1.010 | 1.020 | 1.015 | 1.018 | 1.030 | 1.007 | 1.007 | | |
| 11 | 1.030 | 1.026 | 1.019 | 1.026 | 1.019 | 1.025 | 1.019 | 1.027 | | 1.027 | | | |
| 12 | 1.005 | 1.030 | 1.031 | 1.016 | 1.031 | 1.021 | 1.012 | 1.030 | 1.030 | 1.013 | 1.022 | | |
| 13 | 1.025 | 1.025 | 1.016 | 1.019 | 1.022 | 1.016 | 1.018 | 1.028 | 1.026 | 1.026 | 1.026 | | |
| 14 | 1.029 | 1.014 | 1.020 | 1.004 | 1.004 | 1.019 | 1.022 | 1.025 | | | | | |
| 15 | 1.016 | 1.005 | 1.016 | 1.016 | 1.022 | 1.018 | 1.019 | 1.007 | 1.017 | 1.016 | 1.020 | | 1.033 |
| 16 | 1.009 | 1.015 | 1.026 | 1.029 | 1.025 | 1.025 | 1.027 | 1.029 | 1.028 | 1.027 | | | |
| 17 | 1.030 | 1.034 | | | | | | | | | | | |
| 18 | 1.018 | 1.017 | 1.021 | 1.016 | 1.010 | 1.021 | 1.020 | 1.010 | 1.025 | 1.022 | 1.021 | | |
| 19 | 1.026 | 1.031 | 1.028 | 1.019 | 1.015 | 1.013 | 1.016 | 1.019 | 1.021 | 1.014 | 1.018 | | |
| 20 | 1.027 | 1.028 | 1.025 | 1.022 | 1.020 | 1.017 | 1.016 | | 1.032 | 1.017 | 1.028 | 1.013 | |
| 21 | 1.021 | 1.025 | 1.016 | 1.025 | | 1.019 | 1.021 | 1.009 | 1.026 | 1.026 | 1.028 | 1.029 | |
| Summary: | Urine: Specific Gravity | | | | | | | | | | | | |
| Average | 1.023 | 1.023 | 1.031 | 1.030 | 1.026 | 1.027 | 1.019 | 1.029 | 1.029 | 1.022 | 1.032 | 1.031 | 1.018 |
| Std Dev | 0.008 | 0.008 | 0.006 | 0.008 | 0.007 | 0.006 | 0.005 | 0.008 | 0.006 | 0.006 | 0.007 | 0.007 | 0.007 |
| Max | 1.027 | 1.034 | 1.031 | 1.030 | 1.031 | 1.027 | 1.027 | 1.030 | 1.032 | 1.028 | 1.032 | 1.031 | 1.033 |
| Min | 1.005 | 1.005 | 1.008 | 1.004 | 1.004 | 1.005 | 1.005 | 1.007 | 1.013 | 1.007 | 1.007 | 1.013 | 1.018 |

Figure 48: SD & Range Charts for Urine: Specific Gravity

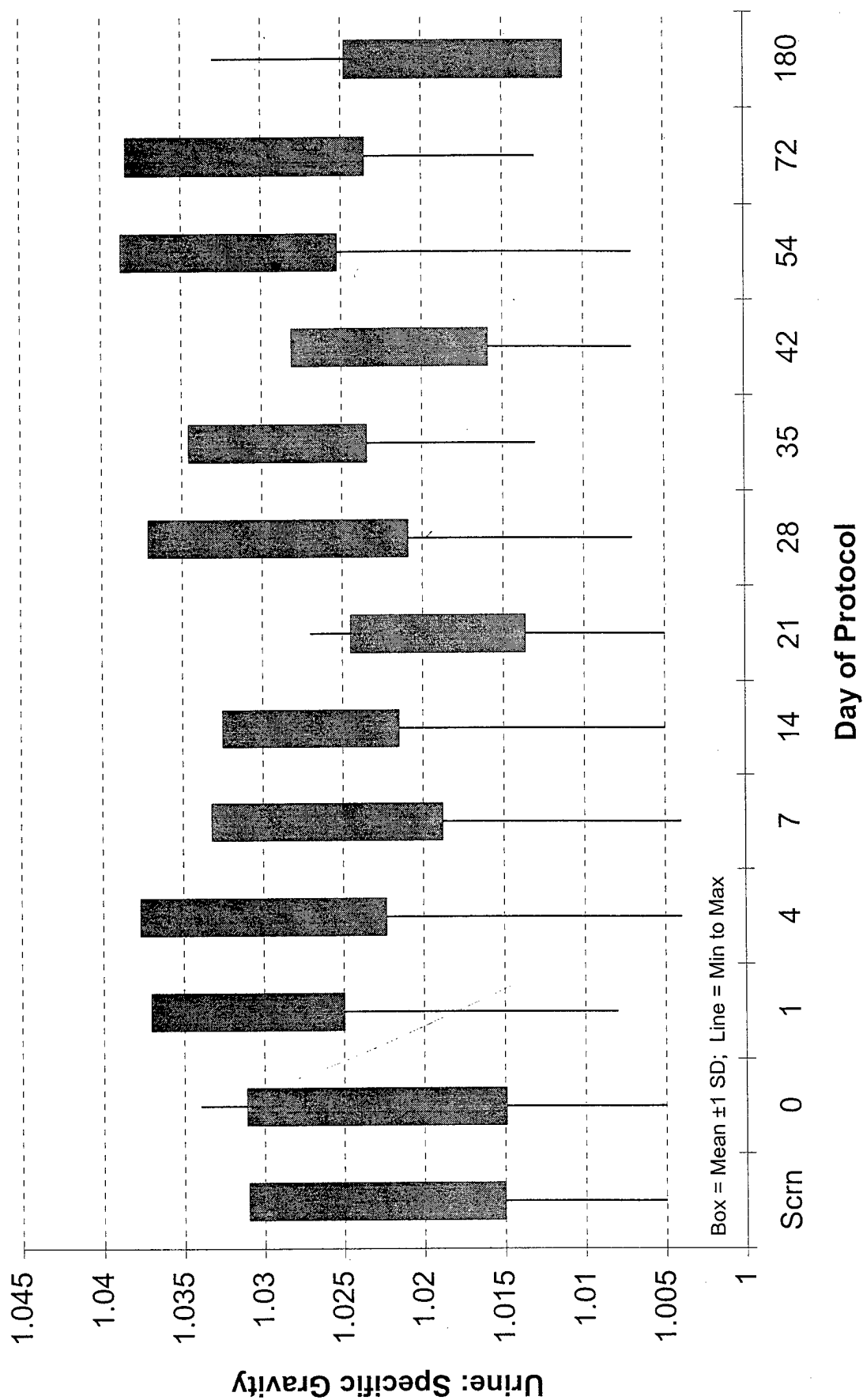


Figure 49a: Pharmacokinetics of Halofantrine Accumulation

| Subject | Accumulation Rate Constant (/day) | | Accumulation Half-time (days) | |
|----------|-----------------------------------|------------|-------------------------------|------------|
| | Halo (+) | Halo (-) | Halo (+) | Halo (-) |
| 1 | 0.101 | 0.086 | 6.89 | 8.10 |
| 2 | 0.058 | 0.048 | 11.88 | 14.30 |
| 4 | 0.392 | 0.730 | 1.77 | 0.95 |
| 5 | 0.160 | 0.159 | 4.33 | 4.35 |
| 7 | 0.139 | 0.211 | 4.97 | 3.28 |
| 8 | 0.058 | 0.060 | 12.00 | 11.63 |
| 9 | 0.126 | 0.116 | 5.49 | 5.99 |
| 10 | 0.038 | 0.056 | 18.26 | 12.43 |
| 11 | 0.262 | | 2.65 | |
| 15 | 0.096 | 0.050 | 7.23 | 13.80 |
| 16 | 0.062 | 0.064 | 11.10 | 10.79 |
| 18 | 0.284 | 0.318 | 2.44 | 2.18 |
| 19 | 0.379 | 0.340 | 1.83 | 2.04 |
| 20 | 0.095 | 0.158 | 7.29 | 4.38 |
| Mean: | 0.161 | 0.184 | 7.01 | 7.25 |
| SD: | 0.120 | 0.191 | 4.80 | 4.82 |
| p-value: | 0.27 | | 0.90 | |

Based on exponential curve fit during administration of Halofantrine
p-values from paired Student t-test

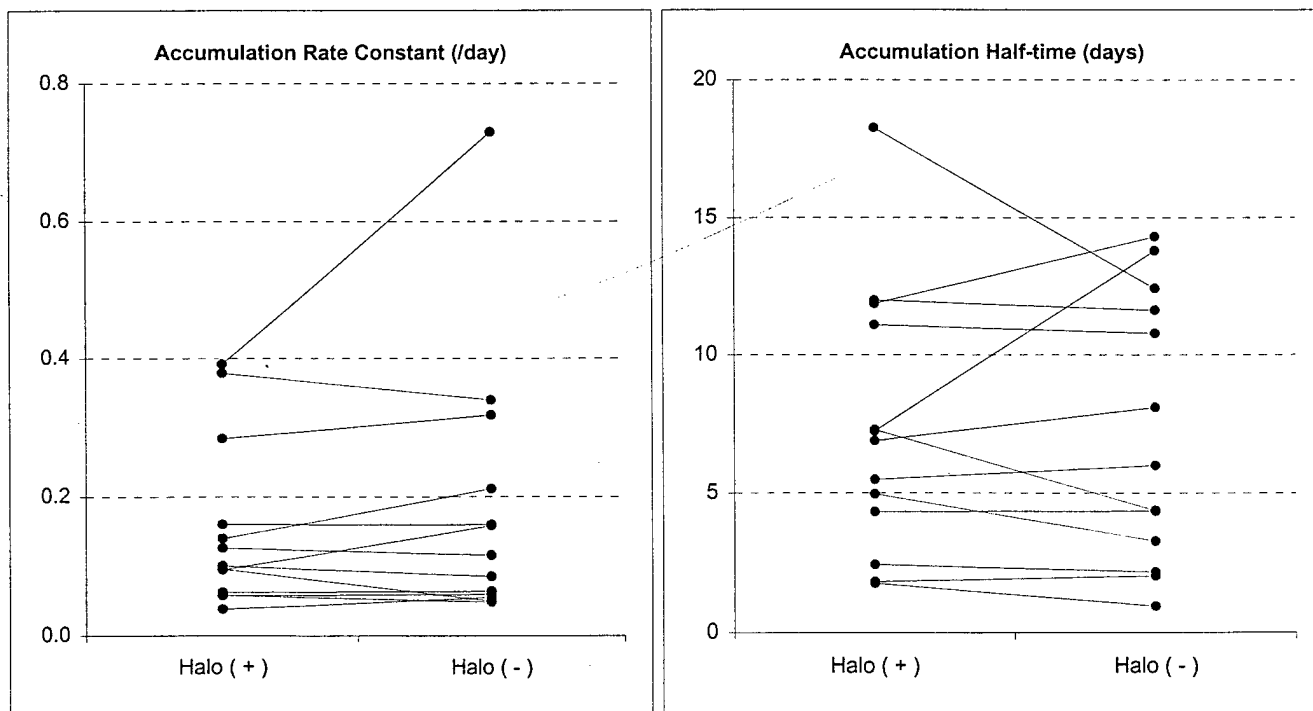


Figure 49b: Halofantrine Kinetics for Subject 01

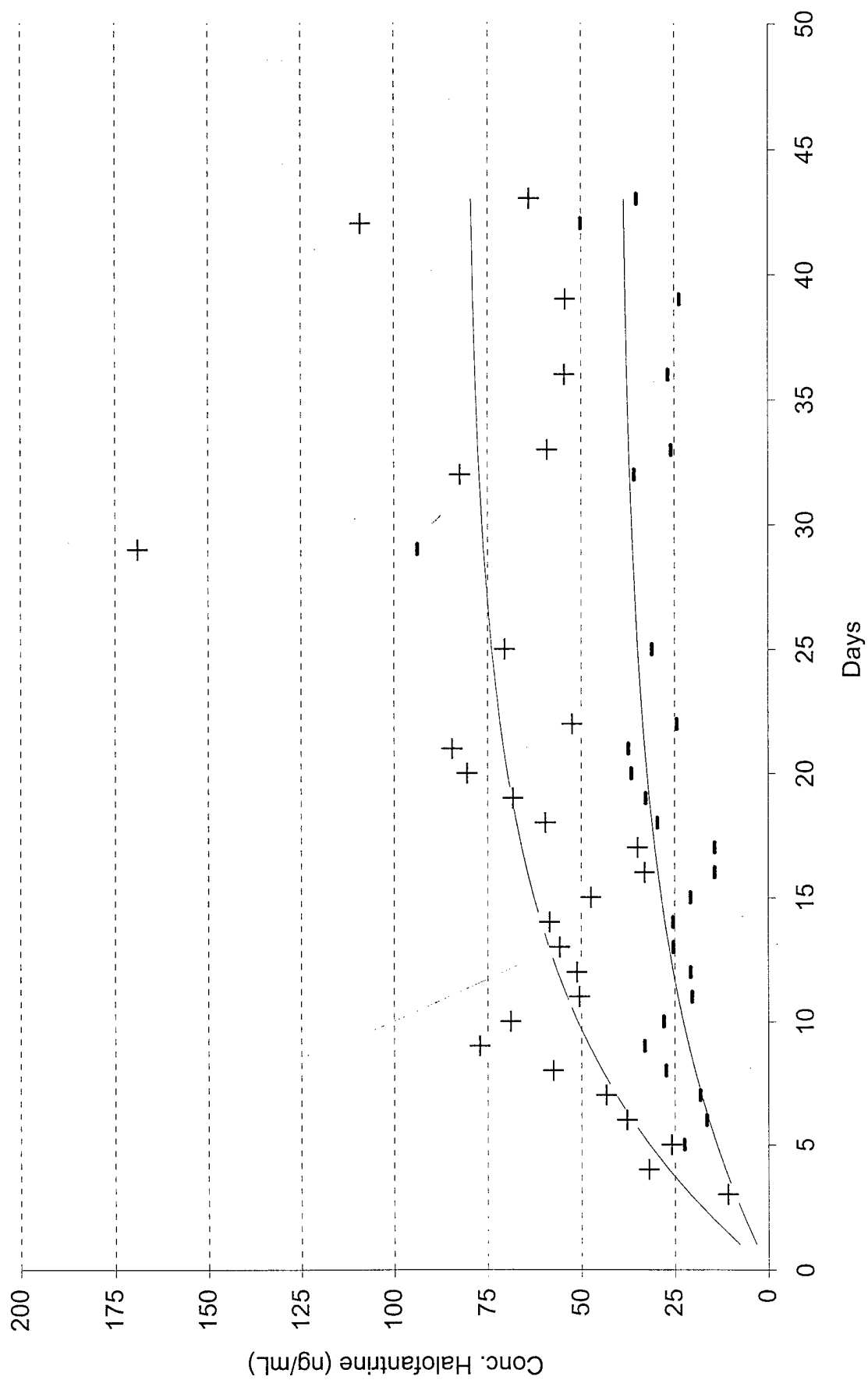


Figure 49c: Halofantrine Kinetics for Subject 02

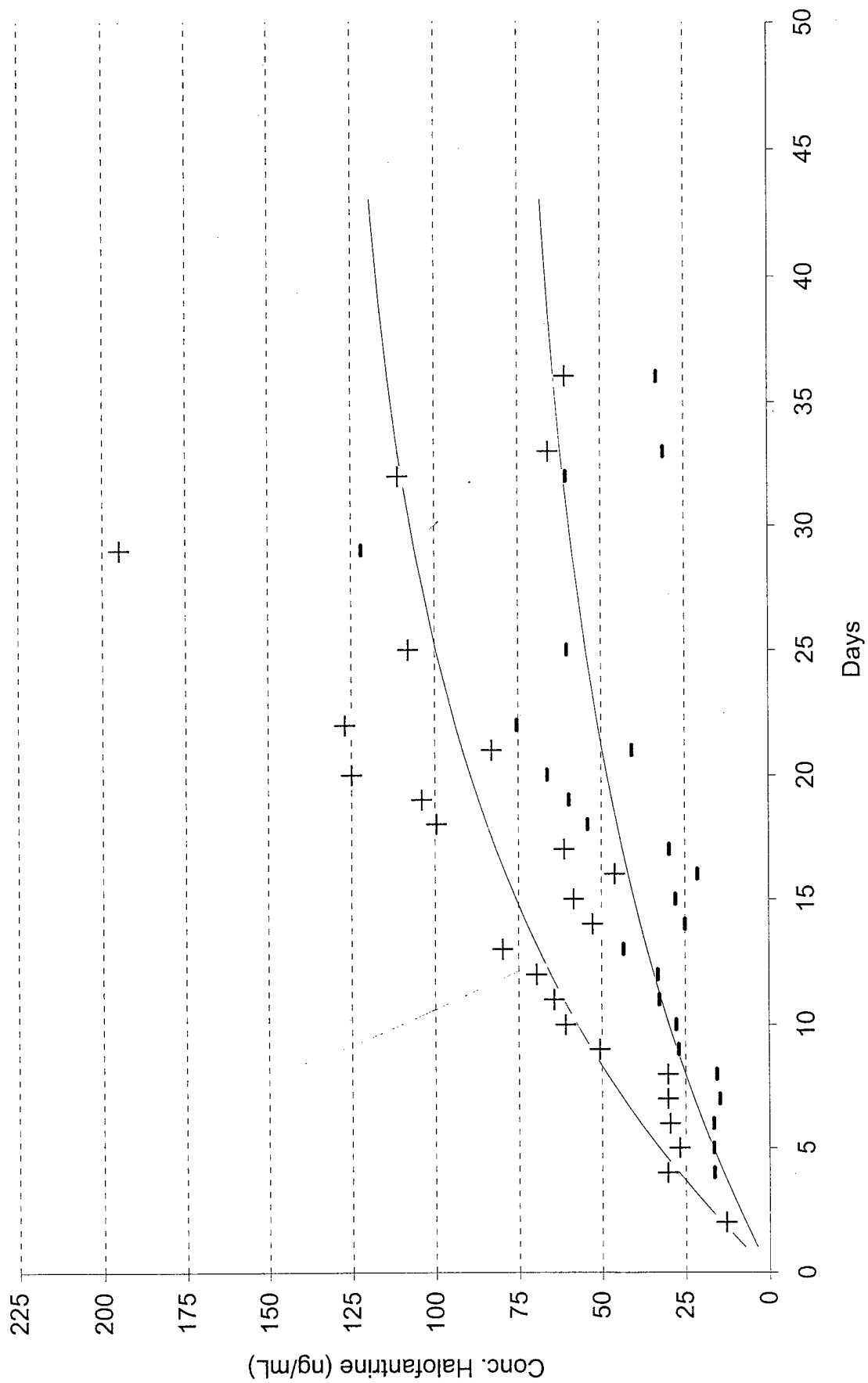


Figure 49d: Halofantrine Kinetics for Subject 04

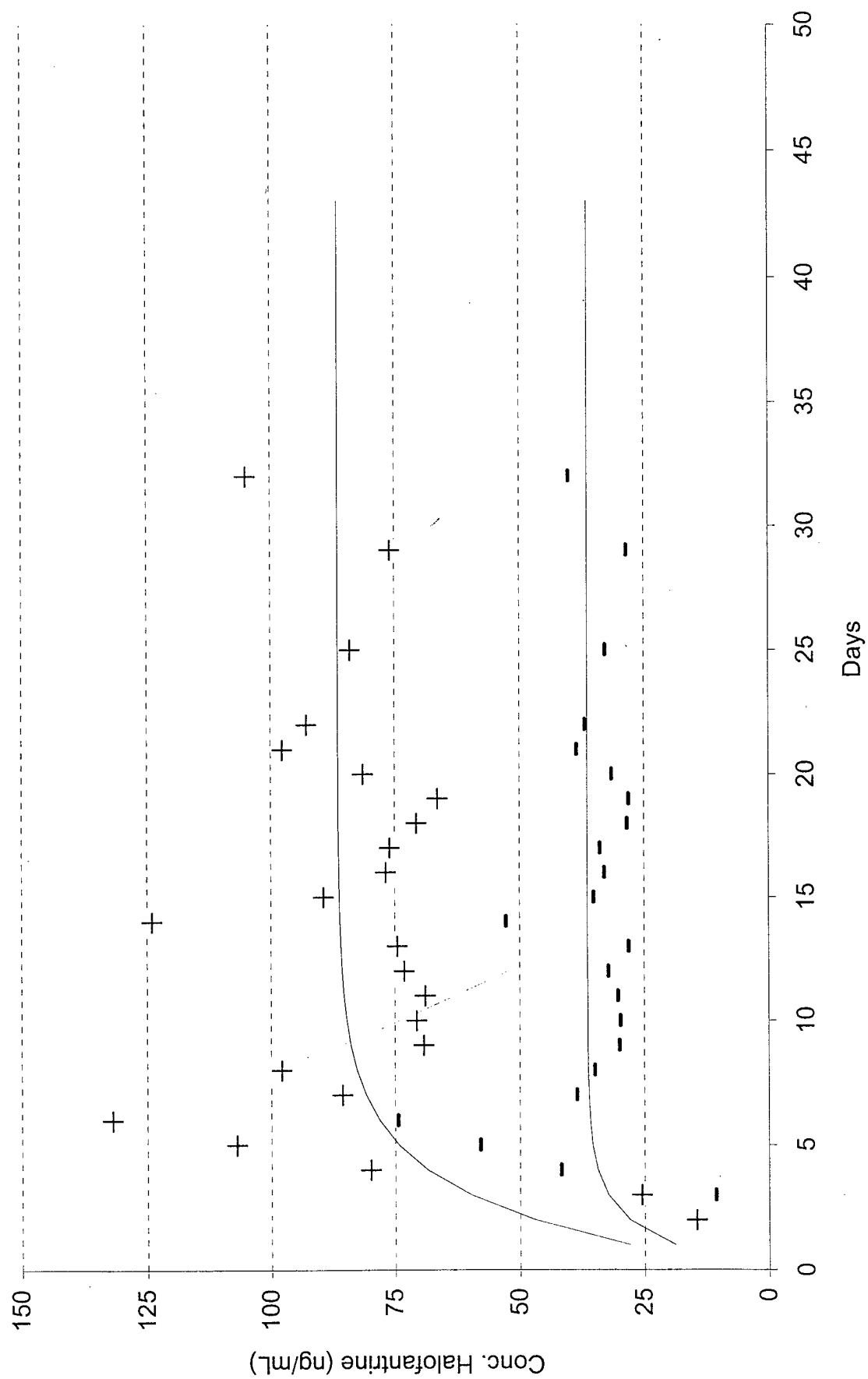


Figure 49e: Halofantrine Kinetics for Subject 05

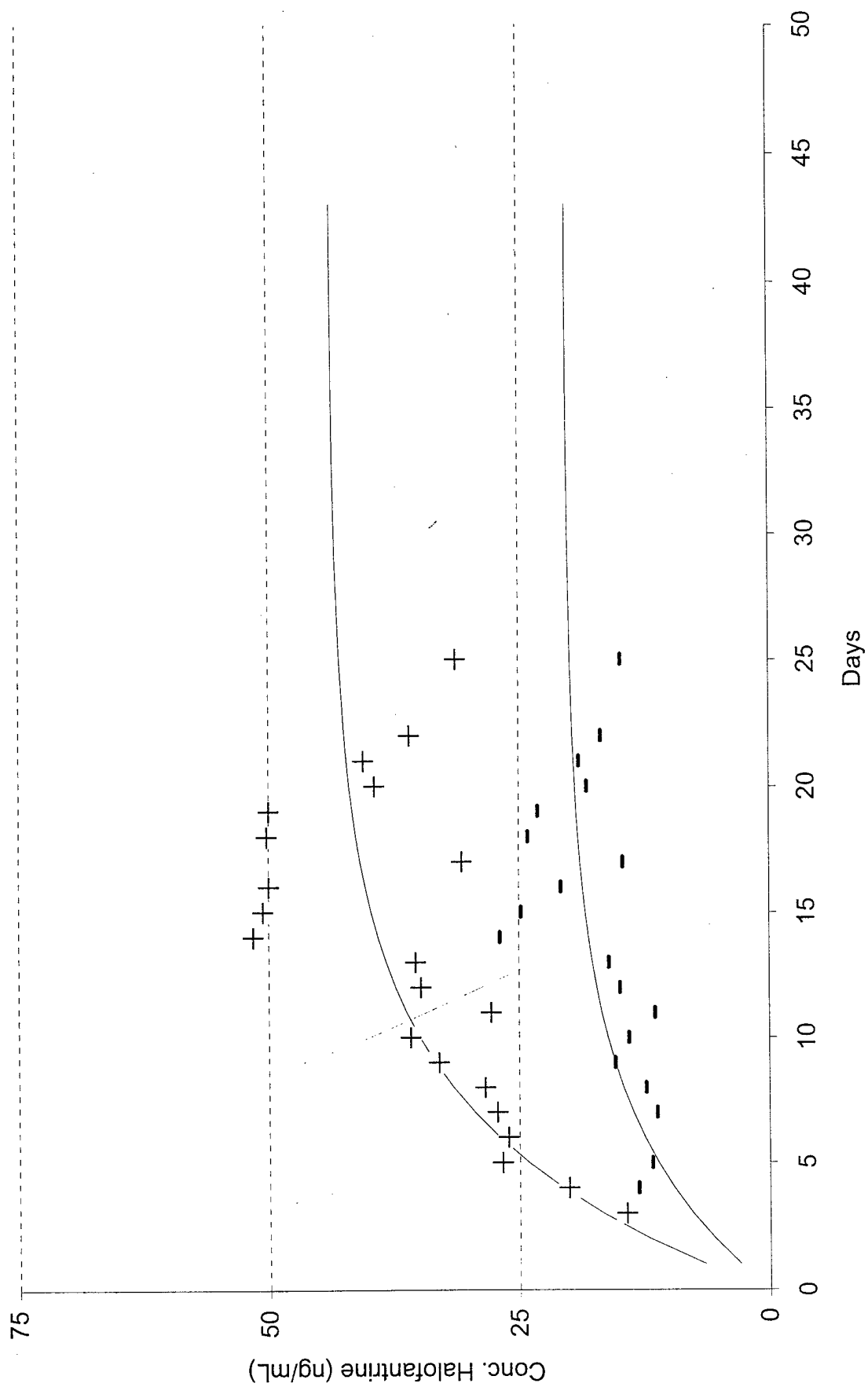


Figure 49f: Halofantrine Kinetics for Subject 07

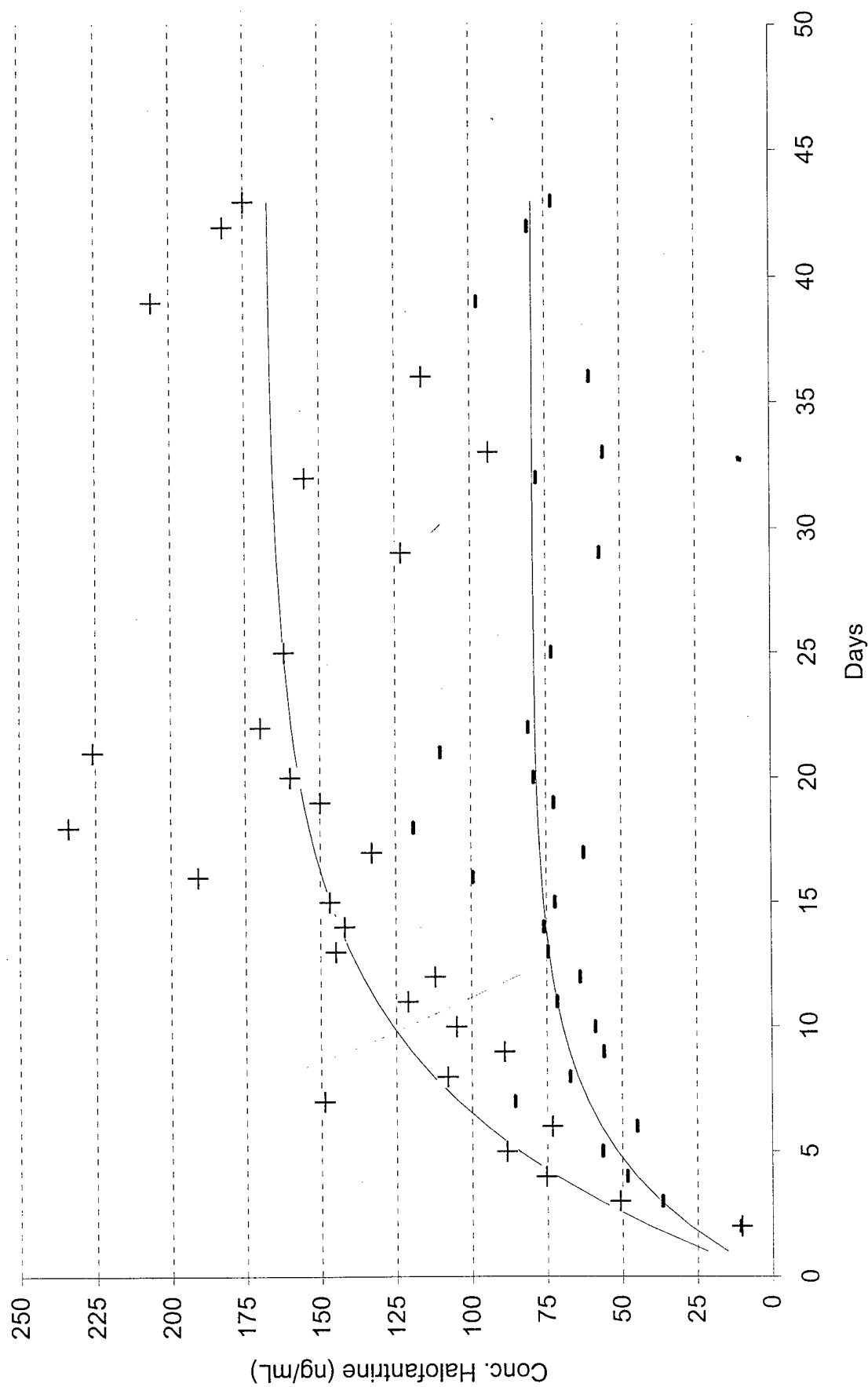


Figure 49g: Halofantrine Kinetics for Subject 08

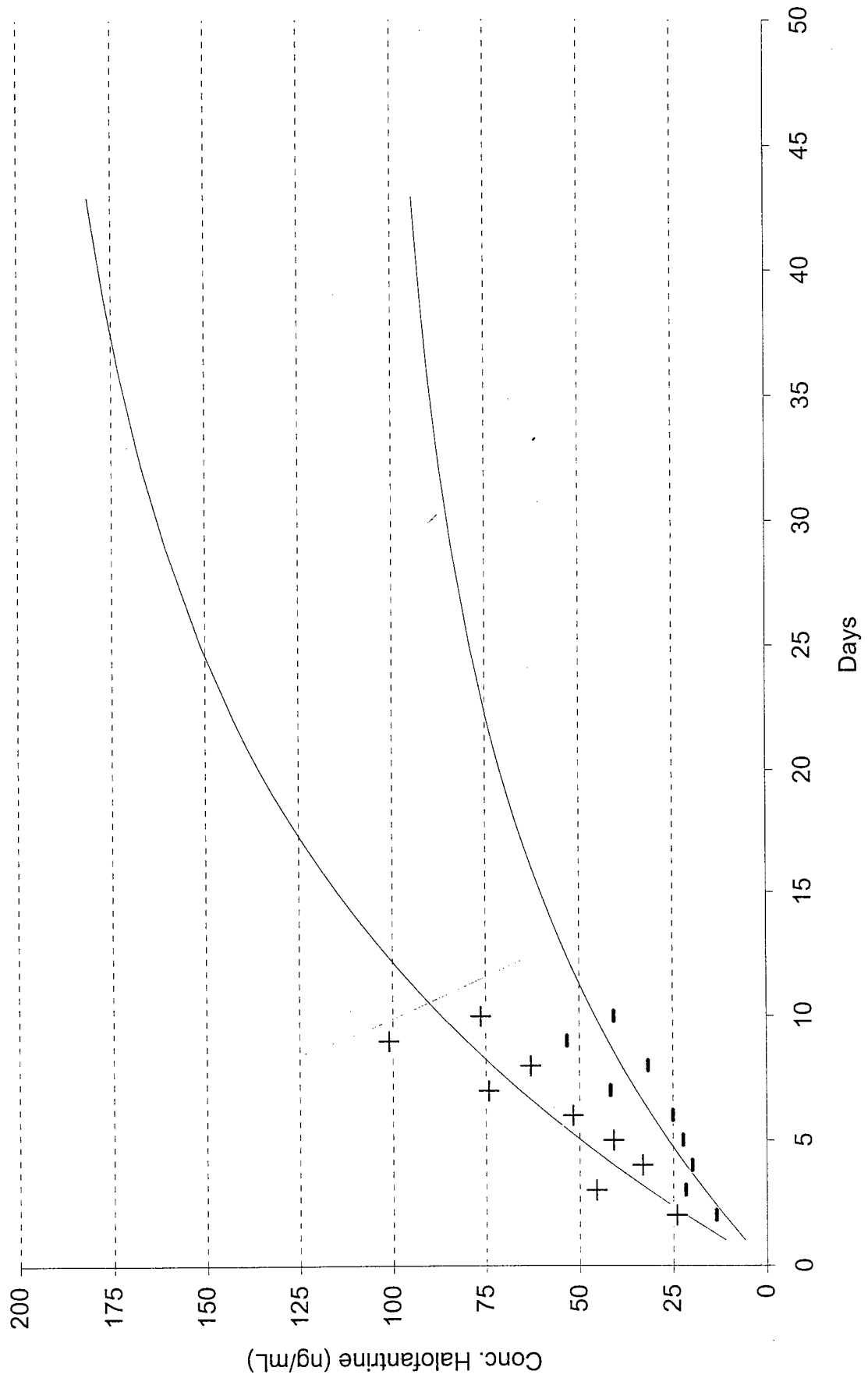


Figure 49h: Halofantrine Kinetics for Subject 09

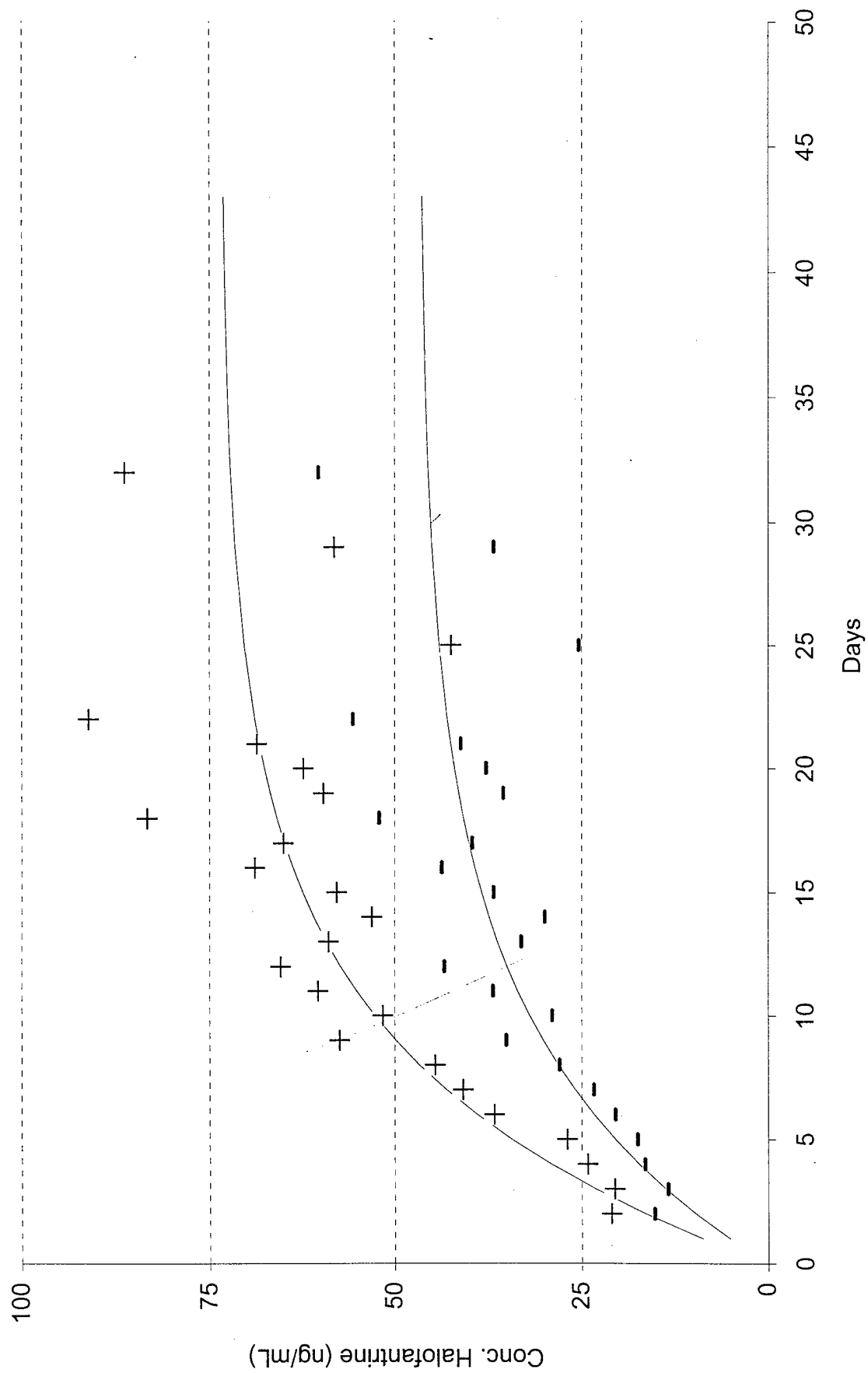


Figure 49i: Halofantrine Kinetics for Subject 10

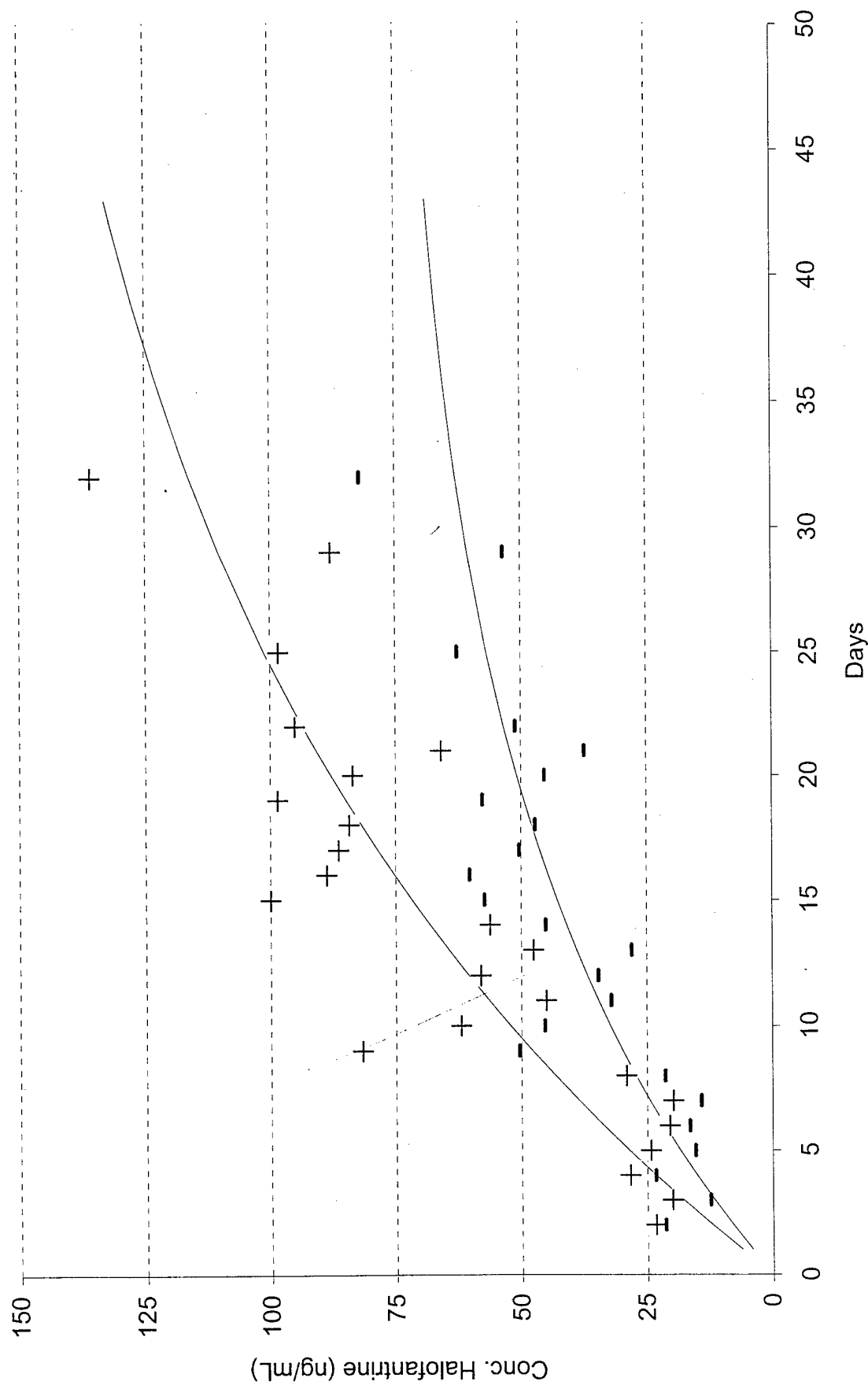


Figure 49j: Halofantrine Kinetics for Subject 11

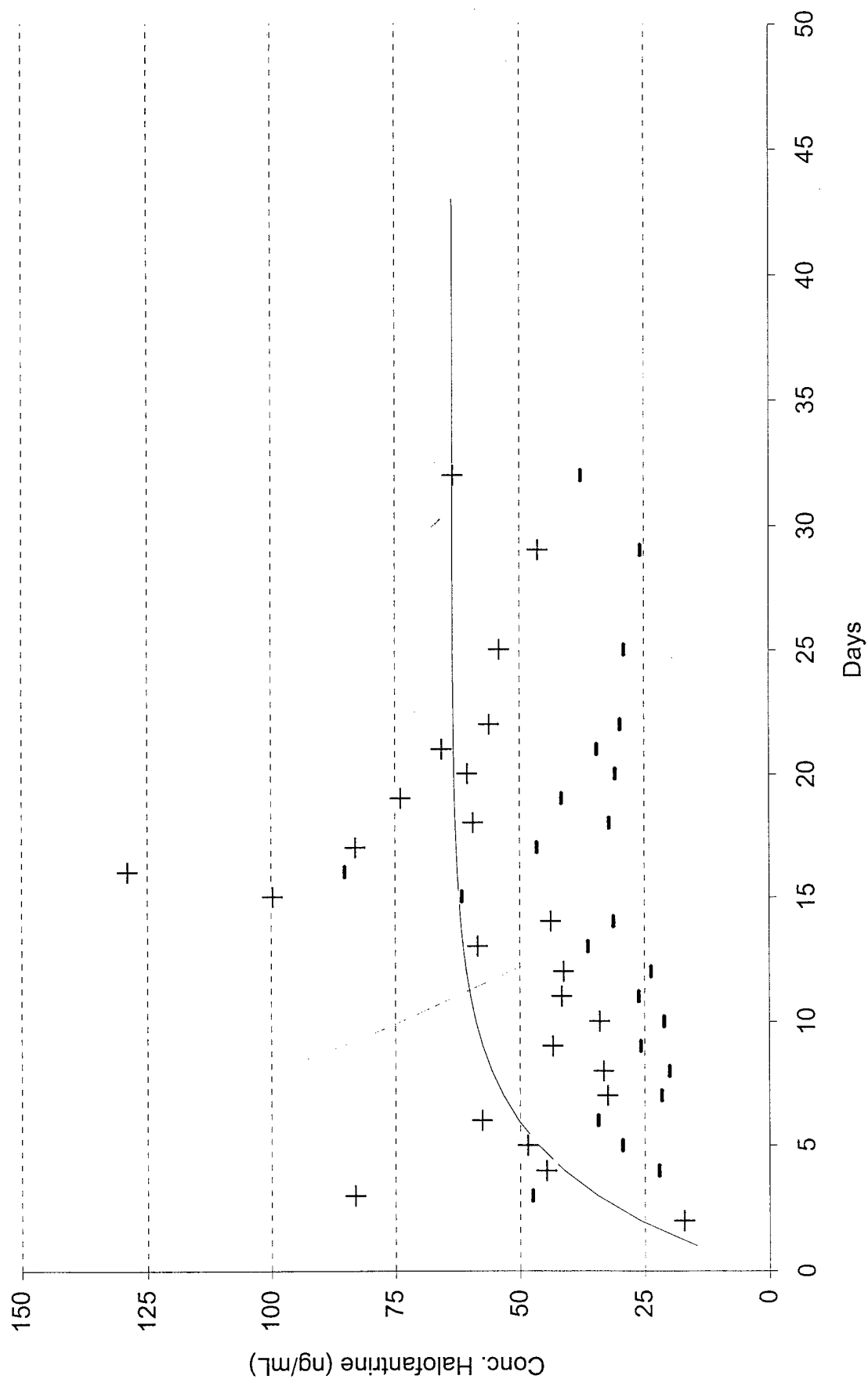


Figure 49k: Halofantrine Kinetics for Subject 14

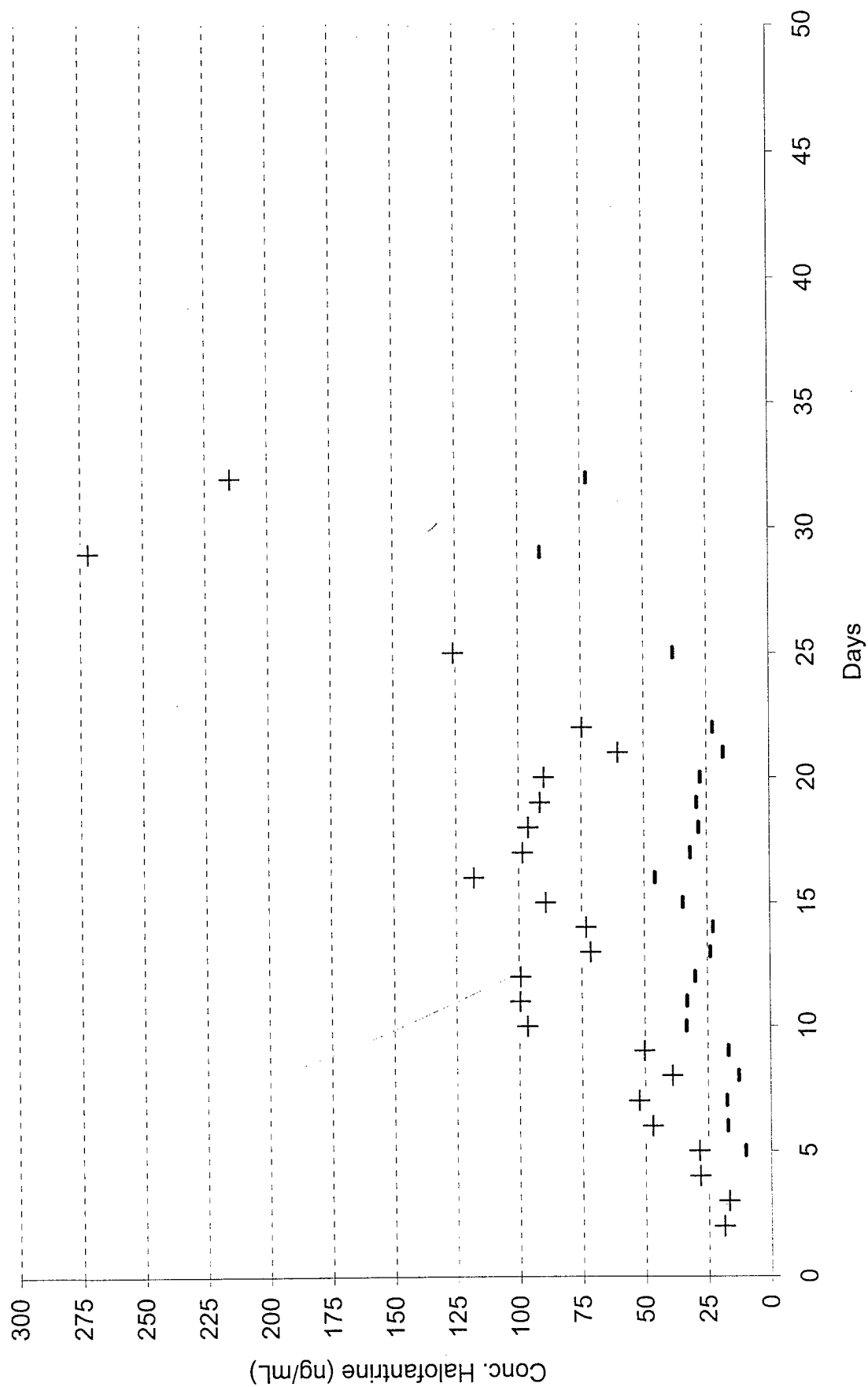


Figure 49L: Halofantrine Kinetics for Subject 15

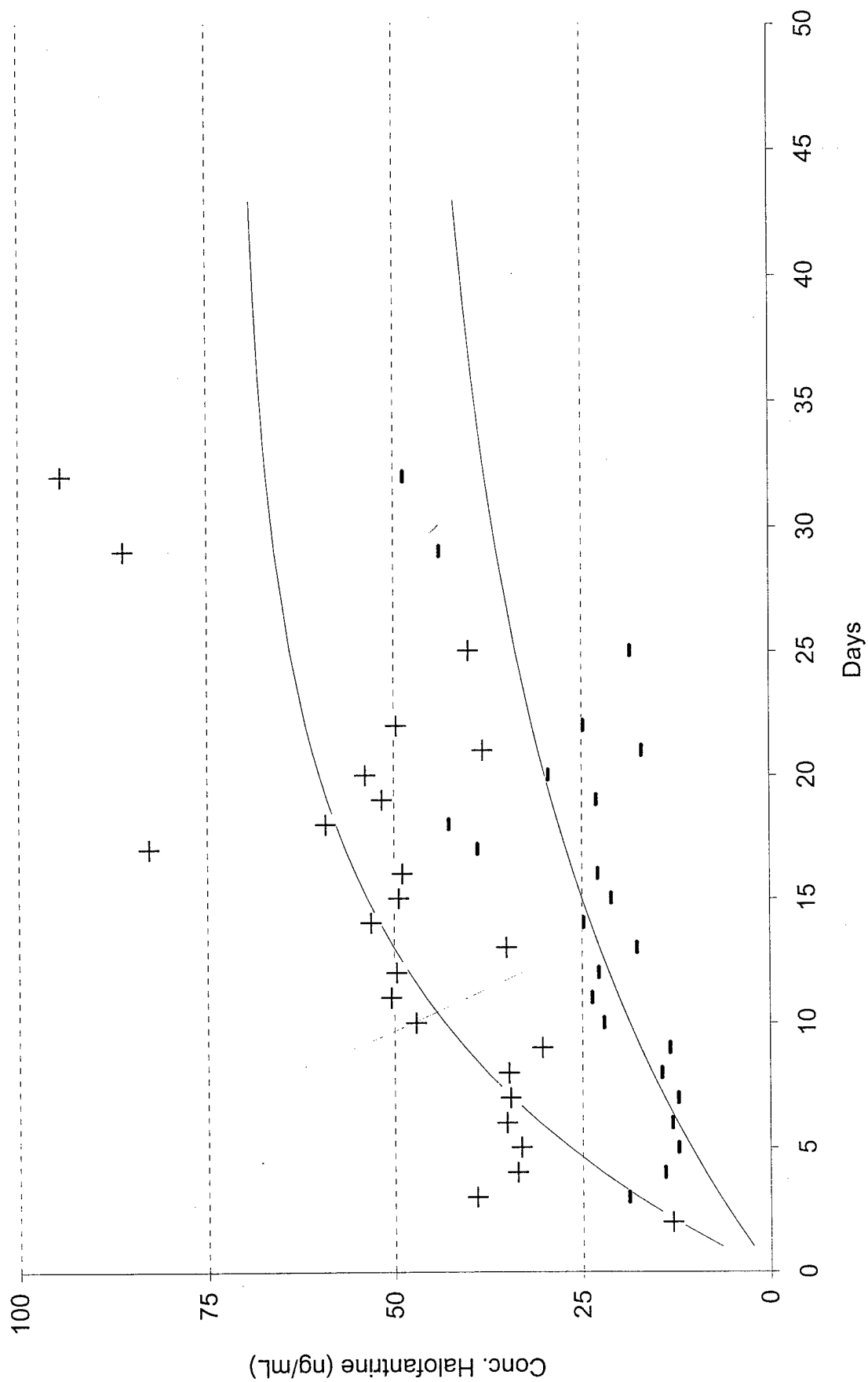


Figure 49m: Halofantrine Kinetics for Subject 16

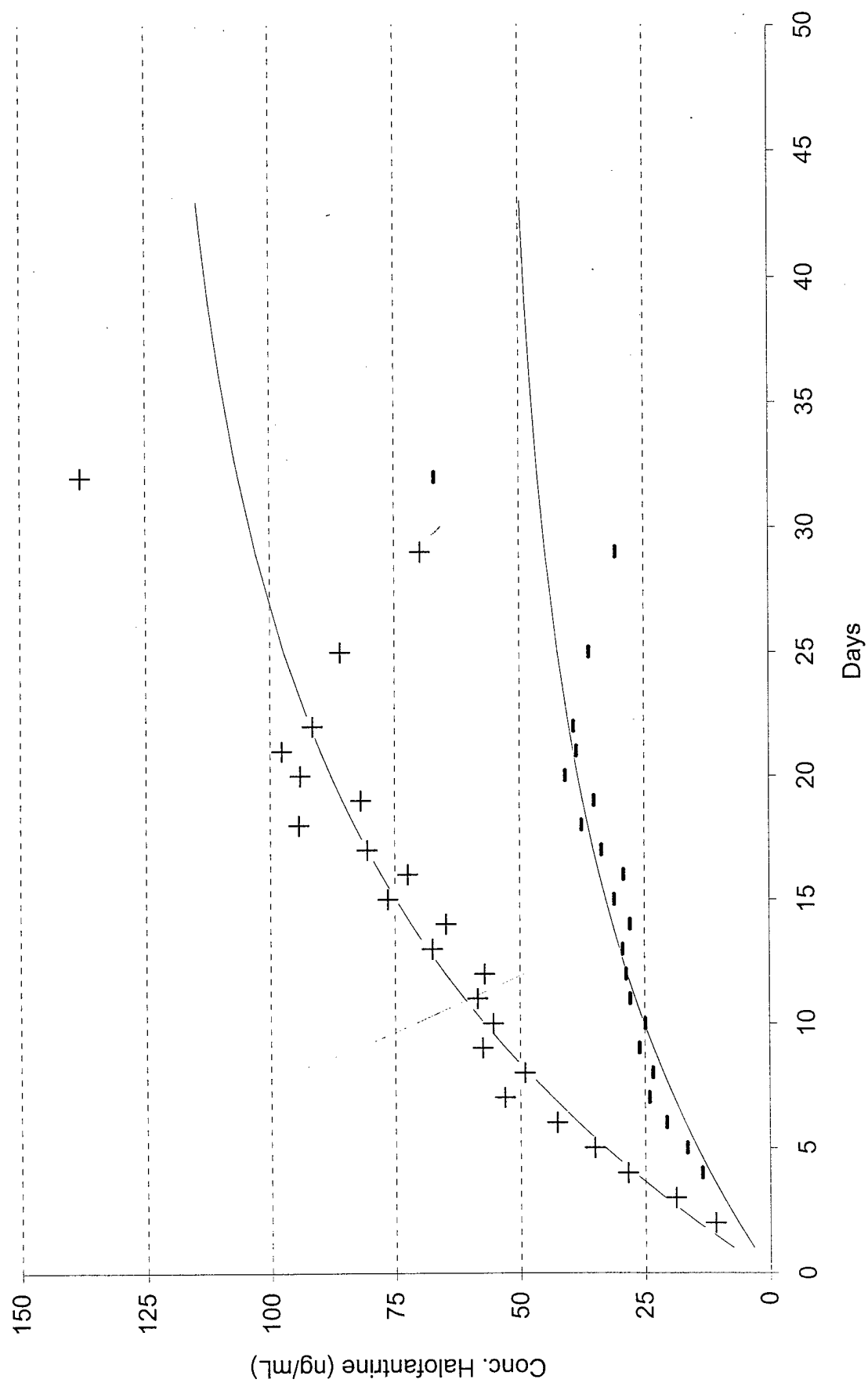


Figure 49n: Halofantrine Kinetics for Subject 18

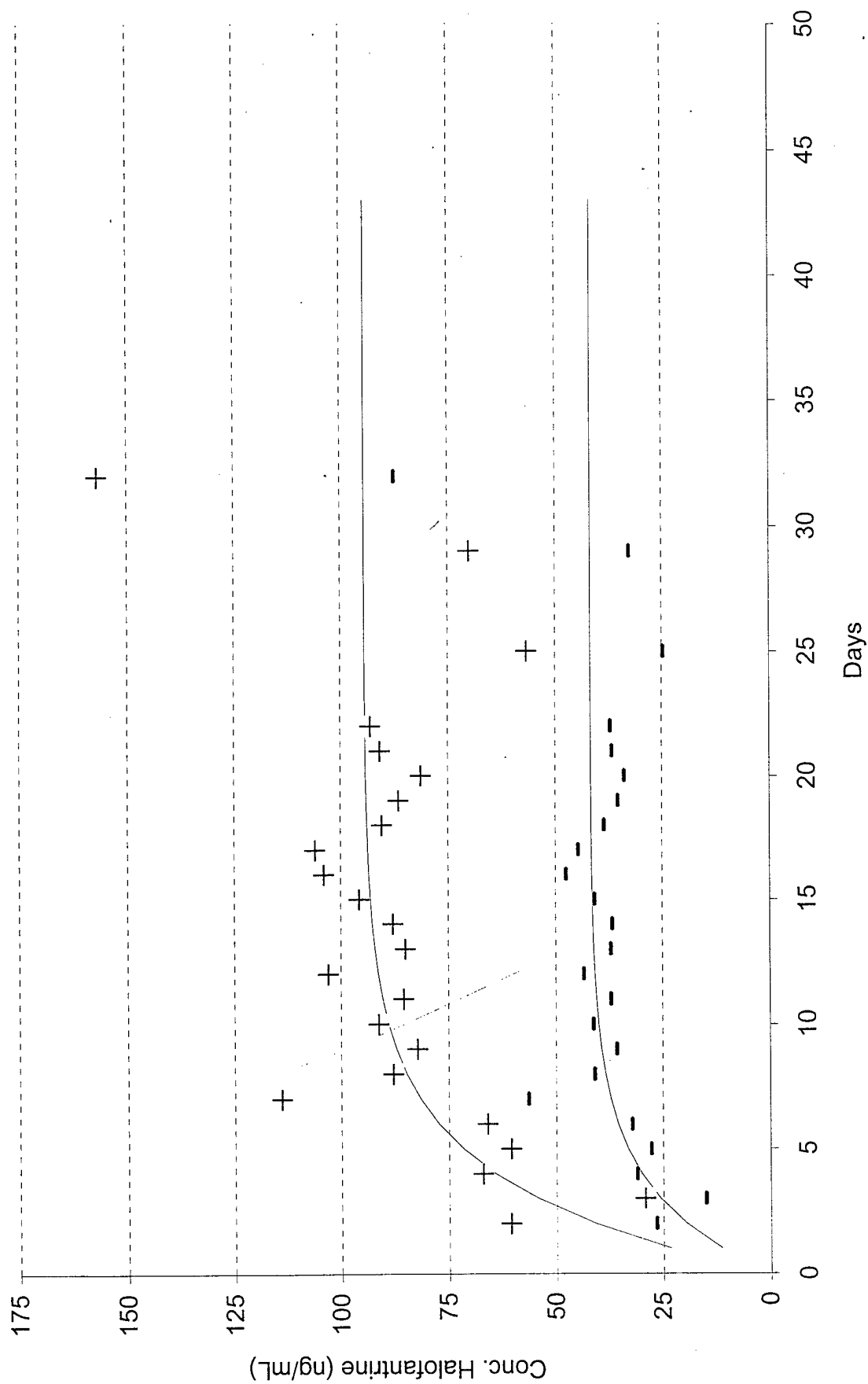


Figure 49o: Halofantrine Kinetics for Subject 19

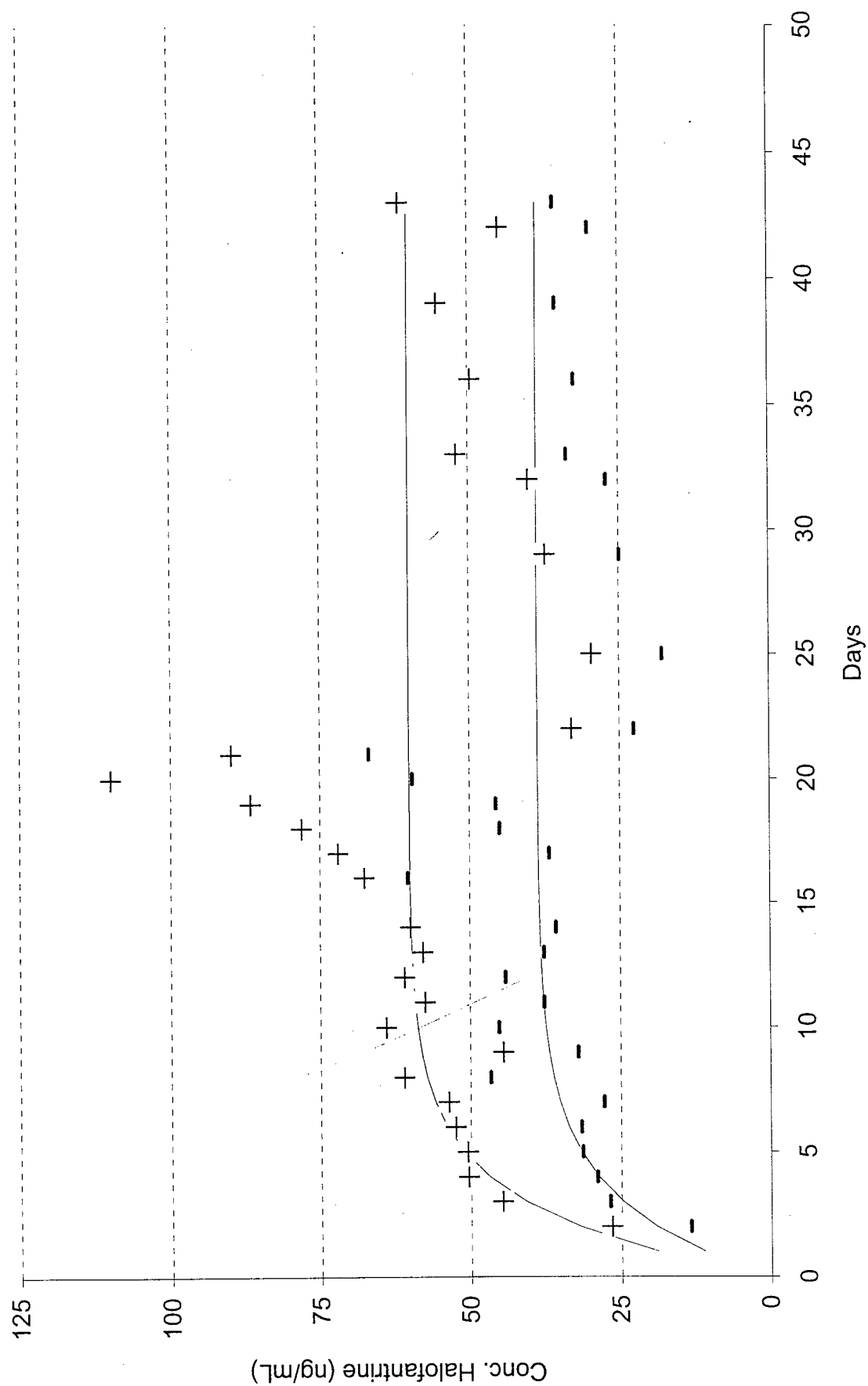


Figure 49p: Halofantrine Kinetics for Subject 20

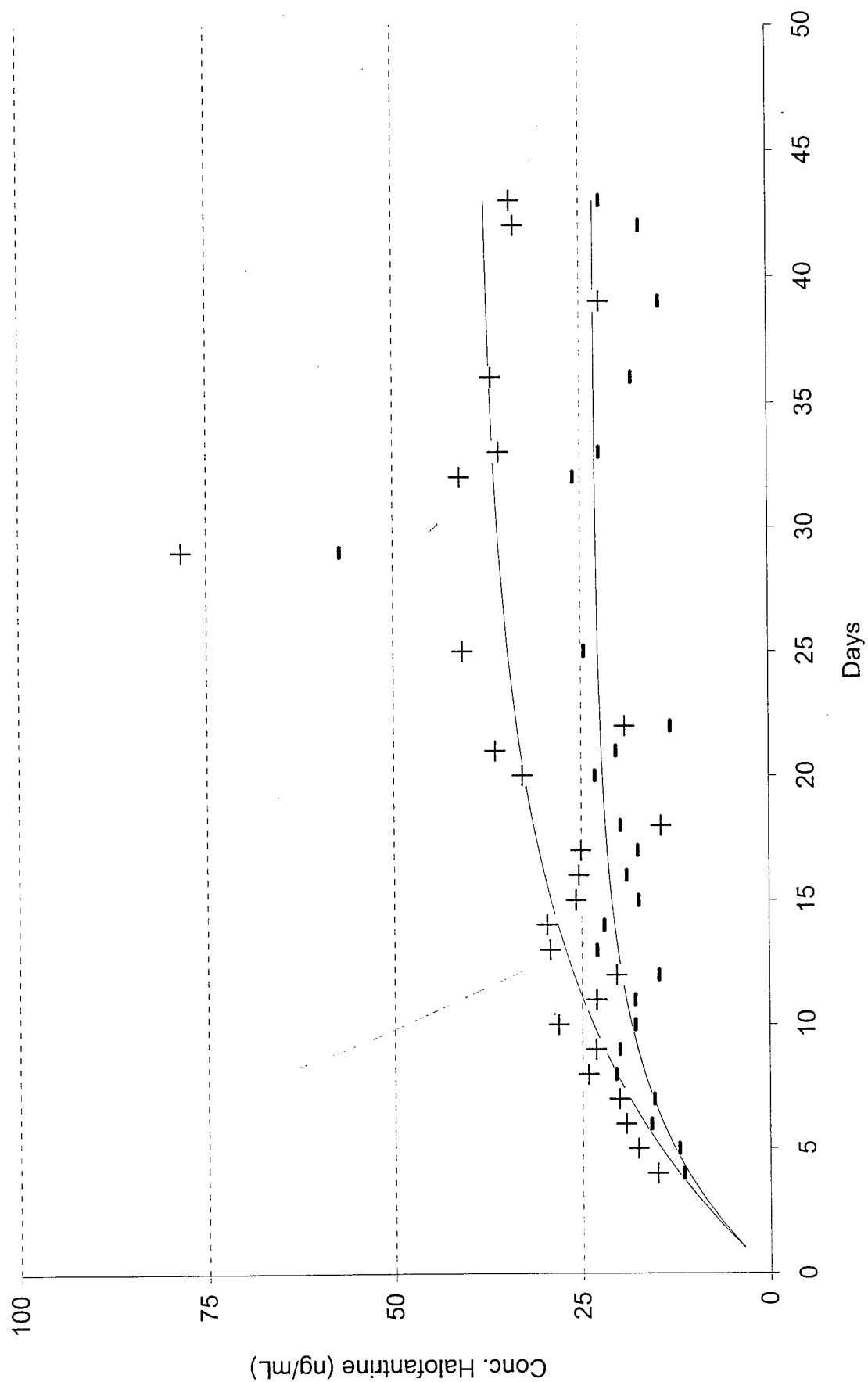
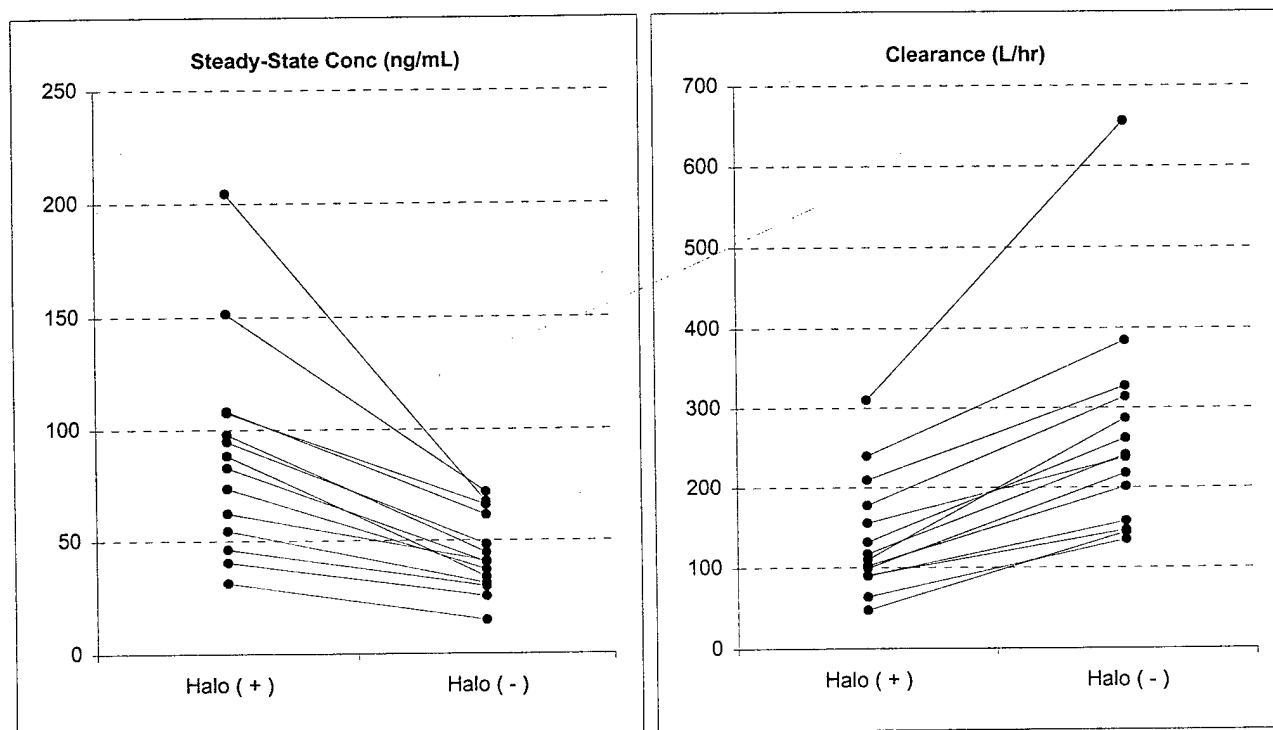


Figure 50: Pharmacokinetics of Halofantrine Clearance

| Subject | Steady-State Conc (ng/mL) | | Clearance (L/hr) | |
|----------|---------------------------|------------|------------------|------------|
| | Halo (+) | Halo (-) | Halo (+) | Halo (-) |
| 1 | 82.9 | 40.3 | 117.1 | 241.0 |
| 2 | 108.1 | 61.5 | 89.8 | 157.9 |
| 4 | 88.3 | 33.8 | 109.9 | 287.0 |
| 5 | 31.3 | 14.8 | 310.2 | 656.0 |
| 7 | 151.6 | 71.9 | 64.0 | 135.1 |
| 9 | 62.3 | 40.8 | 155.8 | 238.0 |
| 10 | 107.4 | 66.1 | 90.4 | 146.9 |
| 11 | 54.6 | 30.9 | 177.7 | 314.2 |
| 14 | 204.3 | 67.4 | 47.5 | 144.0 |
| 15 | 73.6 | 37.0 | 131.9 | 262.2 |
| 16 | 97.9 | 44.6 | 99.2 | 217.8 |
| 18 | 94.6 | 48.3 | 102.6 | 201.1 |
| 19 | 46.3 | 29.7 | 209.8 | 327.4 |
| 20 | 40.5 | 25.3 | 240.0 | 384.5 |
| Mean: | 88.8 | 43.7 | 139.0 | 265.2 |
| SD: | 46.2 | 17.3 | 73.0 | 135.4 |
| p-value: | 0.000 | | 0.000 | |

Based on an average infusion rate of 233 mg/day of each isomer
p-values from paired Student t-test



Units: BPM

Table 12a-1
ECG: Rate

Blank = Not Obtained

| Subj | Scrn | Day 1 Pre | Day 1 .5hr | Day 1 1hr | Day 1 2hr | Day 1 3hr | Day 1 4hr | Day 1 6hr | Day 1 8hr | Day 1 10hr | Day 1 12hr | Day 2 Pre | Day 3 Pre | Day 4 Pre | Day 4 2hr | Day 4 4hr |
|----------|----------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|---------------|--------------|--------------|--------------|--------------|--------------|
| 01 | 87 | 58 | 67 | 72 | 59 | 61 | 67 | 69 | 68 | 74 | 70 | 67 | 62 | 65 | 60 | 71 |
| 02 | 71 | 55 | 51 | 55 | 55 | 66 | 59 | 57 | 65 | 63 | 58 | 58 | 64 | 57 | 68 | 64 |
| 03 | 60 | 60 | 58 | 55 | 59 | 58 | 63 | 58 | 60 | 56 | 53 | 60 | 58 | 54 | 55 | 62 |
| 04 | 79 | 69 | 71 | 69 | 66 | 64 | 67 | 71 | 69 | 67 | 73 | 70 | 64 | 70 | 75 | 77 |
| 05 | 60 | 56 | 51 | 52 | 58 | 51 | 52 | 61 | 58 | 60 | 60 | 56 | 50 | 57 | 54 | 61 |
| 06 | 72 | 64 | 59 | 57 | 55 | 69 | 66 | 54 | 55 | 64 | 54 | 53 | 54 | 59 | 54 | 70 |
| 07 | 58 | 46 | 41 | 41 | 51 | 52 | 47 | 44 | 46 | 45 | 46 | 41 | 49 | 59 | 50 | 66 |
| 08 | 61 | 55 | 51 | 57 | 57 | 57 | 59 | 59 | 54 | 51 | 61 | 54 | 53 | 50 | 55 | 62 |
| 09 | 51 | 49 | 50 | 51 | 52 | | 55 | 63 | 57 | 58 | 57 | 50 | 48 | 58 | 53 | 63 |
| 10 | 68 | 59 | 59 | 62 | 64 | 72 | 70 | 67 | 64 | 75 | 62 | 65 | 64 | 66 | 71 | 77 |
| 11 | 92 | 84 | 86 | 83 | 88 | 89 | 98 | 86 | 96 | 93 | 85 | 76 | 64 | 67 | 66 | 71 |
| 12 | 59 | 60 | 60 | 58 | 58 | 70 | 77 | 63 | 65 | 67 | 60 | 57 | 52 | 54 | 51 | 63 |
| 13 | 51 | 46 | 44 | 46 | 45 | 56 | 54 | 52 | 57 | 53 | 51 | 48 | 44 | 46 | 52 | 52 |
| 14 | 49 | 45 | 45 | 46 | 44 | 48 | 47 | 44 | 43 | 47 | 44 | 45 | 44 | 45 | 47 | 49 |
| 15 | 68 | 65 | 67 | 60 | 74 | 62 | 83 | 73 | 66 | 66 | 64 | 73 | 67 | 57 | 72 | 66 |
| 16 | 74 | 78 | 72 | 70 | 66 | 76 | 72 | 69 | 60 | 66 | 71 | 70 | 65 | 78 | 71 | 77 |
| 17 | 55 | 59 | 53 | 57 | 59 | 67 | 68 | 67 | | | | | | | | |
| 18 | 68 | 58 | 56 | 55 | 58 | 65 | 63 | 64 | 67 | 76 | 66 | 58 | 61 | 63 | 62 | 72 |
| 19 | 69 | 58 | 61 | 62 | 61 | 60 | 69 | 68 | 60 | 72 | 64 | 68 | 63 | 73 | 74 | 82 |
| 20 | | 50 | 46 | 52 | 52 | 52 | 64 | 62 | 55 | 54 | 55 | 49 | 58 | 50 | 53 | 59 |
| 21 | 67 | 62 | 58 | 59 | 59 | 63 | 70 | 69 | 65 | 65 | 66 | 64 | 57 | 63 | 63 | 64 |
| Summary: | ECG: Rate, BPM | | | | | | | | | | | | | | | |
| Average | 66 | 59 | 57 | 58 | 59 | 63 | 65 | 63 | 62 | 64 | 61 | 59 | 57 | 60 | 60 | 66 |
| Std Dev | 11 | 10 | 11 | 10 | 10 | 10 | 12 | 10 | 11 | 11 | 10 | 10 | 07 | 09 | 09 | 08 |
| Max | 92 | 84 | 86 | 83 | 88 | 89 | 98 | 86 | 96 | 93 | 85 | 76 | 67 | 78 | 75 | 82 |
| Min | 49 | 45 | 41 | 41 | 44 | 48 | 47 | 44 | 43 | 45 | 44 | 41 | 44 | 45 | 47 | 49 |

Units: BPM

Table 12a-2
ECG: Rate

Blank = Not Obtained

| Subj | Day 4 6hr | Day 4 8hr | Day 4 12hr | Day 5 PRE | Day 6 Pre | Day 7 Pre | Day 7 2hr | Day 7 4hr | Day 7 6hr | Day 7 8hr | Day 7 12hr | Day 8 Pre | Day 9 Pre | Day 10 Pre | Day 11 Pre | Day 12 Pre |
|----------|--------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|--------------|---------------|---------------|---------------|
| 01 | 86 | 64 | 74 | 62 | 67 | 56 | 64 | 62 | 65 | 57 | 69 | 67 | 59 | 58 | 53 | 61 |
| 02 | 79 | 69 | 71 | 64 | 62 | 61 | 55 | 62 | 68 | 106 | 80 | 61 | 53 | 54 | 57 | 61 |
| 03 | 60 | 68 | 62 | 52 | 54 | 57 | 62 | 65 | 62 | 60 | 61 | 61 | 54 | 54 | 56 | 68 |
| 04 | 71 | 93 | 79 | 68 | 69 | 74 | 66 | 71 | 78 | 72 | 71 | 69 | 75 | 68 | 73 | 75 |
| 05 | 68 | 59 | 52 | 46 | 55 | 54 | 49 | 54 | 67 | 52 | 55 | 55 | 50 | 50 | 49 | 56 |
| 06 | 66 | 68 | 65 | 57 | 53 | 65 | 54 | 75 | 70 | 58 | 64 | 59 | 58 | 54 | 64 | 61 |
| 07 | 51 | 52 | 55 | 47 | 67 | 59 | 54 | 72 | 64 | 57 | 69 | 58 | 65 | 65 | 62 | 57 |
| 08 | 61 | 58 | 58 | 54 | 51 | 52 | 54 | 62 | 58 | 57 | 60 | 56 | 56 | 57 | | |
| 09 | 59 | 56 | 58 | 51 | 49 | 53 | 51 | 67 | 61 | 56 | 60 | 50 | 57 | 54 | 48 | 53 |
| 10 | 69 | 67 | 76 | 65 | 75 | 68 | 73 | 77 | 74 | 94 | 71 | 72 | 60 | 90 | 75 | 67 |
| 11 | 67 | 74 | 73 | 65 | 64 | 64 | 61 | 74 | 67 | 65 | 65 | 62 | 61 | 60 | 64 | 60 |
| 12 | 63 | 56 | 56 | 64 | 64 | 55 | 56 | 65 | 66 | 65 | 64 | 66 | 72 | 61 | 62 | 61 |
| 13 | 60 | 51 | 54 | 47 | 53 | 50 | 50 | 59 | 52 | 57 | 61 | 53 | 50 | 47 | 46 | 45 |
| 14 | 47 | 48 | 41 | 45 | 48 | 47 | 45 | 51 | 50 | 46 | 46 | 48 | 45 | 45 | 42 | 47 |
| 15 | 63 | 57 | 55 | 59 | 66 | 69 | 63 | 67 | 58 | 62 | 61 | 58 | 59 | 57 | 62 | 55 |
| 16 | 79 | 65 | 73 | 79 | 64 | 65 | 68 | 78 | 76 | 73 | 69 | 74 | 67 | 66 | 78 | 65 |
| 17 | | | | | | | | | | | | | | | | |
| 18 | 70 | 66 | 64 | 63 | 61 | 70 | 65 | 77 | 78 | 72 | 68 | 63 | 67 | 62 | 65 | 61 |
| 19 | 79 | 76 | 64 | 68 | 66 | 63 | | 73 | 69 | 68 | 62 | 56 | 66 | 64 | 57 | 62 |
| 20 | 58 | 55 | 59 | 51 | 53 | 51 | 55 | 64 | 59 | 58 | 55 | 55 | 56 | 52 | 56 | 55 |
| 21 | 75 | 66 | 67 | 64 | 60 | 57 | 55 | 65 | 64 | 68 | 71 | 58 | 59 | 56 | 58 | 56 |
| Summary: | | | | | | | | | | | | | | | | |
| Average | 67 | 63 | 63 | 59 | 60 | 60 | 58 | 67 | 65 | 65 | 64 | 60 | 59 | 59 | 59 | 59 |
| Std Dev | 10 | 10 | 10 | 09 | 08 | 08 | 07 | 08 | 08 | 14 | 07 | 07 | 08 | 10 | 10 | 07 |
| Max | 86 | 93 | 79 | 79 | 75 | 74 | 73 | 78 | 78 | 106 | 80 | 74 | 75 | 90 | 78 | 75 |
| Min | 47 | 48 | 41 | 45 | 48 | 47 | 45 | 51 | 50 | 46 | 46 | 48 | 45 | 45 | 42 | 45 |

Units: BPM

Table 12a-3
ECG: Rate

Blank = Not Obtained

| Subj | Day 13 Pre | Day 14 Pre | Day 14 2hr | Day 14 4hr | Day 14 6hr | Day 14 8hr | Day 14 12hr | Day 15 Pre | Day 16 Pre | Day 17 Pre | Day 18 Pre | Day 19 Pre | Day 20 Pre | Day 21 Pre |
|----------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| 01 | 66 | 59 | 59 | 59 | 64 | 66 | 64 | 57 | 63 | 57 | 65 | 80 | 64 | 68 |
| 02 | 52 | 54 | 67 | 60 | 76 | 67 | 71 | 63 | 53 | 63 | 54 | 54 | 56 | 58 |
| 03 | 64 | 68 | 62 | 56 | 70 | 63 | 65 | 61 | 60 | 61 | 59 | 59 | 52 | 57 |
| 04 | 68 | 73 | 74 | 76 | 83 | 83 | 84 | 79 | 76 | 77 | 98 | 81 | 76 | 75 |
| 05 | 58 | 53 | 54 | 65 | 58 | 52 | 51 | 51 | 53 | 54 | 58 | 56 | 54 | 52 |
| 06 | 57 | 56 | 54 | 71 | 68 | 65 | 63 | 66 | 61 | 68 | 66 | 60 | 59 | 60 |
| 07 | 59 | 68 | 61 | 68 | 72 | 84 | 65 | 70 | 63 | 67 | 64 | 65 | 67 | 85 |
| 08 | | | | | | | | | | | | | | |
| 09 | 56 | 45 | 59 | 60 | 55 | 54 | 57 | 53 | 50 | 56 | 50 | 49 | 56 | 51 |
| 10 | 59 | 75 | 64 | 75 | 73 | 80 | 65 | 62 | 69 | 61 | 88 | 79 | 67 | 71 |
| 11 | 54 | 66 | 63 | 74 | 70 | 71 | 79 | 61 | 64 | 62 | 62 | 64 | 67 | 65 |
| 12 | 63 | 59 | 59 | 56 | 57 | 63 | 76 | 67 | 61 | 63 | 67 | 65 | 59 | 62 |
| 13 | 46 | 42 | 49 | 60 | 44 | 91 | 58 | 50 | 50 | 49 | 55 | 48 | 43 | 44 |
| 14 | 42 | 45 | 44 | 51 | 51 | 48 | 49 | 46 | 44 | 46 | 46 | 45 | 50 | 49 |
| 15 | 58 | 55 | 56 | 71 | 65 | 58 | 56 | 54 | 51 | 52 | 61 | 69 | 57 | 54 |
| 16 | 81 | 64 | 65 | 78 | 80 | 65 | 72 | 70 | 71 | 78 | 70 | 70 | 71 | 75 |
| 17 | | | | | | | | | | | | | | |
| 18 | 70 | 65 | 68 | 89 | 95 | 82 | 85 | 68 | 67 | 62 | 67 | 65 | 68 | 74 |
| 19 | 58 | 62 | | | | | | 63 | 56 | 57 | 57 | 61 | 60 | 57 |
| 20 | 55 | 54 | 56 | 59 | 58 | 62 | 63 | 54 | 53 | 55 | 54 | 55 | 54 | 58 |
| 21 | 58 | 52 | 57 | 64 | 69 | 61 | 68 | 55 | 54 | 55 | 59 | 60 | 55 | 54 |
| Summary: | | | | | | | | | | | | | | |
| Average | 59 | 59 | 60 | 66 | 67 | 68 | 66 | 61 | 59 | 60 | 63 | 62 | 60 | 62 |
| Std Dev | 09 | 09 | 07 | 10 | 12 | 12 | 10 | 08 | 08 | 08 | 12 | 10 | 08 | 11 |
| Max | 81 | 75 | 74 | 89 | 95 | 91 | 85 | 79 | 76 | 78 | 98 | 81 | 76 | 85 |
| Min | 42 | 42 | 44 | 51 | 44 | 48 | 49 | 46 | 44 | 46 | 46 | 45 | 43 | 44 |

Units: BPM

Table 12a-4
ECG: Rate

Blank = Not Obtained

| Subj | Day 21 2hr | Day 21 4hr | Day 21 6hr | Day 21 8hr | Day 21 12hr | Day 22 Pre | Day 25 Pre | Day 29 Pre | Day 32 Pre | Day 36 Pre | Day 39 Pre | Day 42 Pre | Day 42 .5hr | Day 42 1hr |
|----------|---------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|
| 01 | 56 | 75 | 71 | 76 | 75 | 82 | 73 | 73 | 75 | 63 | 72 | 57 | 63 | 59 |
| 02 | 51 | 53 | 64 | 72 | 73 | 72 | 77 | 68 | 109 | 80 | 68 | | | |
| 03 | 49 | 51 | 56 | 53 | 63 | 54 | 52 | 59 | 62 | 58 | 66 | 56 | 61 | 62 |
| 04 | 75 | 88 | 82 | 85 | 78 | 85 | 81 | 72 | 75 | 75 | | | | |
| 05 | 54 | 63 | 55 | 57 | 56 | 55 | 53 | | | | | | | |
| 06 | 64 | 76 | 78 | 76 | 69 | 70 | 77 | 67 | 73 | 62 | 64 | 58 | 57 | 56 |
| 07 | 68 | 68 | 69 | 66 | 69 | 65 | 79 | 59 | 75 | 53 | 68 | 59 | 55 | 56 |
| 08 | | | | | | | | | | | | | | |
| 09 | 61 | 64 | 63 | 61 | 60 | 60 | 72 | 59 | 55 | 54 | 50 | 47 | 58 | 46 |
| 10 | 65 | 80 | 82 | 76 | 67 | 72 | 75 | 84 | 72 | 57 | 60 | 69 | 59 | 63 |
| 11 | 70 | 80 | 73 | 74 | 72 | 66 | 71 | 77 | 70 | | 73 | 64 | 63 | 60 |
| 12 | 59 | 66 | 67 | 68 | 67 | 65 | 74 | 70 | 70 | 61 | 70 | 59 | 62 | 59 |
| 13 | 43 | 52 | 46 | 49 | 47 | 54 | 62 | 50 | 60 | 54 | 56 | 47 | 48 | 49 |
| 14 | 57 | 52 | 51 | 50 | 49 | 50 | 59 | 58 | 54 | 57 | 56 | | | |
| 15 | 56 | 67 | 63 | 58 | 67 | 55 | 76 | 75 | 71 | 72 | 68 | 60 | 57 | 62 |
| 16 | 64 | 89 | 77 | 73 | 75 | 72 | 76 | 67 | 70 | 72 | 75 | 67 | 63 | 61 |
| 17 | | | | | | | | | | | | | | |
| 18 | 72 | 83 | 85 | 85 | 77 | 72 | 80 | 88 | 81 | | | 57 | 59 | 58 |
| 19 | 59 | 76 | 69 | 65 | 63 | 67 | 60 | 61 | 68 | 69 | 67 | 64 | 61 | 60 |
| 20 | 56 | 64 | 64 | 66 | 60 | 59 | 54 | 56 | 54 | 51 | 54 | 58 | 53 | 54 |
| 21 | 54 | 61 | 58 | 57 | 72 | 56 | 54 | 56 | 61 | 60 | 52 | 52 | 57 | 54 |
| Summary: | | | | | | | | | | | | | | |
| Average | 60 | 69 | 67 | 67 | 66 | 65 | 69 | 67 | 70 | 62 | 64 | 58 | 58 | 57 |
| Std Dev | 08 | 12 | 11 | 11 | 09 | 10 | 10 | 10 | 13 | 09 | 08 | 06 | 04 | 05 |
| Max | 75 | 89 | 85 | 85 | 78 | 85 | 81 | 88 | 109 | 80 | 75 | 69 | 63 | 63 |
| Min | 43 | 51 | 46 | 49 | 47 | 50 | 52 | 50 | 54 | 51 | 50 | 47 | 48 | 46 |

Units: BPM

Table 12a-5
ECG: Rate

Blank = Not Obtained

| Subj | Day 42 2hr | Day 42 3hr | Day 42 4hr | Day 42 6hr | Day 42 8hr | Day 42 10hr | Day 42 12hr | Day 43 AM | Day 44 AM | Day 45 AM | Day 48 AM | Day 51 AM | Day 54 AM | Day 57 AM |
|----------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 01 | 63 | 86 | 70 | 67 | 69 | 76 | 71 | 56 | 58 | 60 | 59 | 54 | 68 | 64 |
| 02 | | | | | | | | | | | | | | |
| 03 | 57 | 62 | 62 | 65 | 53 | 56 | 58 | 73 | 70 | 74 | 69 | 64 | 65 | 61 |
| 04 | | | | | | | | | | | | | | |
| 05 | | | | | | | | | | | | | | |
| 06 | 58 | 58 | 78 | 60 | 59 | 59 | 53 | 59 | 57 | 55 | 64 | 61 | 64 | 63 |
| 07 | 56 | 48 | 59 | 47 | 54 | 59 | 55 | 36 | | 74 | 68 | 65 | 83 | 78 |
| 08 | | | | | | | | | | | | | | |
| 09 | 51 | 55 | 54 | 49 | 53 | 53 | 52 | 50 | 55 | | 54 | 60 | 56 | 69 |
| 10 | 70 | 87 | 76 | 63 | 59 | 70 | 72 | 71 | 79 | | 70 | 81 | 81 | |
| 11 | 64 | 75 | 77 | 71 | 68 | 68 | 70 | 68 | 68 | 79 | | | | |
| 12 | 55 | 68 | 61 | 55 | 55 | 58 | 60 | 58 | 61 | 55 | 67 | 74 | 60 | 78 |
| 13 | 52 | 49 | 51 | 45 | 46 | 49 | 49 | 50 | 62 | 64 | 49 | 59 | 62 | 62 |
| 14 | | | | | | | | | | | | | | |
| 15 | 64 | 73 | 71 | 68 | 68 | 71 | 75 | 75 | 69 | 63 | 61 | 78 | 68 | 63 |
| 16 | 57 | 79 | 68 | 76 | 73 | 73 | 75 | 78 | 96 | | | | | |
| 17 | | | | | | | | | | | | | | |
| 18 | 57 | 65 | 64 | 59 | 56 | 62 | 60 | 57 | 73 | 75 | | 80 | 86 | 81 |
| 19 | 61 | 67 | 68 | 63 | 62 | 63 | 62 | 62 | 69 | 65 | 74 | 80 | 74 | 63 |
| 20 | 57 | 59 | 66 | 62 | 63 | 58 | 55 | 58 | 54 | 53 | 58 | 65 | 58 | 51 |
| 21 | 58 | 57 | 63 | 57 | 65 | 64 | 57 | 55 | 71 | 70 | 74 | 93 | 71 | 72 |
| Summary: | | | | | | | | | | | | | | |
| Average | 59 | 66 | 66 | 60 | 60 | 63 | 62 | 60 | 67 | 66 | 64 | 70 | 69 | 67 |
| Std Dev | 05 | 12 | 08 | 09 | 08 | 08 | 09 | 11 | 11 | 09 | 08 | 11 | 10 | 09 |
| Max | 70 | 87 | 78 | 76 | 73 | 76 | 75 | 78 | 96 | 79 | 74 | 93 | 86 | 81 |
| Min | 51 | 48 | 51 | 45 | 46 | 49 | 49 | 36 | 54 | 53 | 49 | 54 | 56 | 51 |

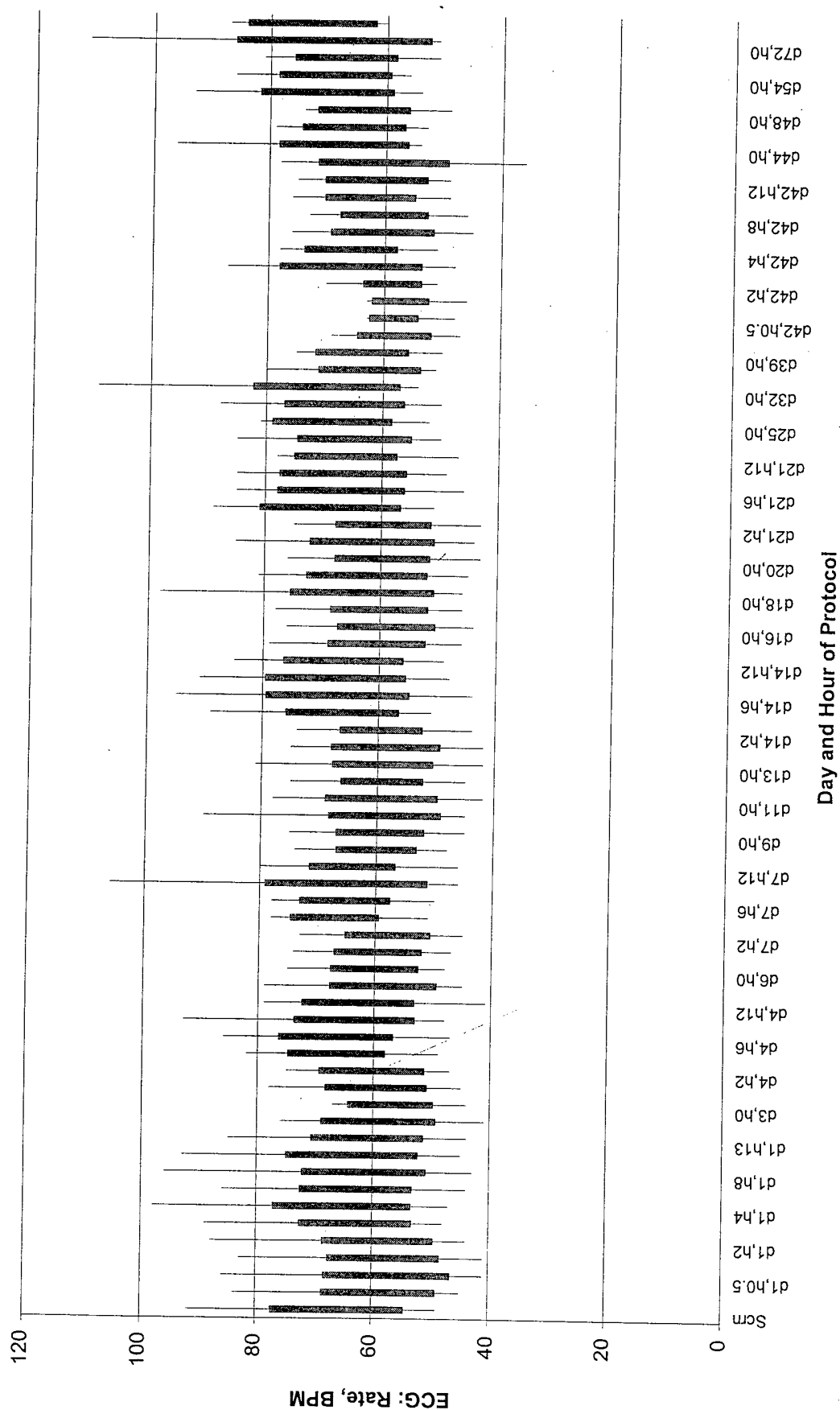
Units: BPM

Table 12a-6
ECG: Rate

Blank = Not Obtained

| Subj | Day 72 AM | Day 180 AM |
|----------|--------------|---------------|
| 01 | 74 | 84 |
| 02 | | |
| 03 | 62 | 60 |
| 04 | | |
| 05 | | |
| 06 | 66 | 83 |
| 07 | 67 | 67 |
| 08 | | |
| 09 | 51 | 62 |
| 10 | | |
| 11 | | |
| 12 | 64 | 69 |
| 13 | 59 | 62 |
| 14 | | |
| 15 | 111 | 87 |
| 16 | 74 | 83 |
| 17 | | |
| 18 | 90 | |
| 19 | 58 | |
| 20 | 55 | |
| 21 | | |
| Summary: | | |
| Average | 69 | 73 |
| Std Dev | 17 | 11 |
| Max | 111 | 87 |
| Min | 51 | 60 |

Figure 51: SD & Range Charts for ECG: Rate, BPM



Units: msec

Blank = Not Obtained

Table 12b-1
ECG - PR Interval

| Subj | Scrn | Day 1 Pre | Day 1 .5hr | Day 1 1hr | Day 1 2hr | Day 1 3hr | Day 1 4hr | Day 1 6hr | Day 1 8hr | Day 1 10hr | Day 1 12hr | Day 2 Pre | Day 3 Pre | Day 4 Pre | Day 4 2hr | Day 4 4hr | Day 4 6hr | Day 4 8hr |
|----------|-------------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 01 | 146 | 138 | 148 | 136 | 156 | 154 | 154 | 136 | 148 | 148 | 142 | 150 | 160 | 170 | 162 | 158 | 146 | 156 |
| 02 | 162 | 162 | 164 | 170 | 168 | 172 | 174 | 166 | 156 | 156 | 168 | 158 | 160 | 152 | 152 | 150 | 152 | 142 |
| 03 | 174 | 162 | 166 | 174 | 154 | 164 | 172 | 172 | 170 | 184 | 184 | 170 | 180 | 196 | 198 | | 186 | 176 |
| 04 | 162 | 156 | 160 | 164 | 162 | 148 | 156 | 160 | 150 | 152 | 156 | 156 | 158 | 158 | 162 | 162 | 168 | 154 |
| 05 | 150 | 160 | 160 | 156 | 150 | 154 | 156 | 148 | 144 | 154 | 160 | 156 | 170 | 166 | 162 | 144 | 150 | 154 |
| 06 | 136 | 142 | 154 | 144 | 146 | 154 | 130 | 124 | 148 | 140 | 136 | 142 | 150 | 136 | 144 | 142 | 140 | 142 |
| 07 | 160 | 148 | 154 | 150 | 134 | 130 | 146 | 158 | 152 | 164 | 158 | 164 | 156 | 154 | 160 | 150 | 156 | 150 |
| 08 | 146 | 150 | 136 | 134 | 128 | 150 | 144 | 136 | 128 | 134 | 120 | 158 | 158 | 162 | 144 | 130 | 138 | 138 |
| 09 | 168 | 170 | 168 | 168 | 160 | | 148 | 148 | 154 | 150 | 154 | 162 | 168 | 166 | 160 | 142 | 148 | 152 |
| 10 | 140 | 144 | 140 | 142 | 142 | 132 | 126 | 132 | 124 | 130 | 138 | 144 | 148 | 114 | 140 | 130 | 143 | 140 |
| 11 | 136 | 130 | 128 | 132 | 132 | 130 | 128 | 130 | 126 | 128 | 128 | 130 | 136 | 136 | 146 | 140 | 138 | 140 |
| 12 | 164 | 164 | 172 | 164 | 162 | 156 | 156 | 166 | 164 | 164 | 170 | 166 | 138 | 176 | 168 | 166 | 166 | 170 |
| 13 | 150 | 152 | 154 | 156 | 150 | 138 | 146 | 142 | 144 | 142 | 144 | 160 | 164 | 164 | 154 | 148 | 140 | 148 |
| 14 | 170 | 170 | 172 | 178 | 180 | 170 | 168 | 174 | 180 | 168 | 174 | 166 | 176 | 182 | 180 | 174 | 164 | 176 |
| 15 | 150 | 146 | 152 | 148 | 148 | 126 | 138 | 146 | 148 | 116 | 150 | 146 | 152 | 150 | 148 | 146 | 148 | 150 |
| 16 | 174 | 182 | 172 | 180 | 178 | 180 | 178 | 178 | 164 | 180 | 174 | 178 | 182 | 178 | 184 | 176 | 180 | 174 |
| 17 | 174 | 178 | 176 | 194 | 176 | 172 | 160 | 160 | | | | | | | | | | |
| 18 | 140 | 142 | 142 | 142 | 144 | 140 | 138 | 130 | 140 | 136 | 140 | 154 | 152 | 154 | 146 | 142 | 142 | 144 |
| 19 | 126 | 136 | 136 | 134 | 134 | 130 | 132 | 134 | 128 | 132 | 128 | 138 | 130 | 136 | 132 | 128 | 124 | 130 |
| 20 | | 142 | 146 | 142 | 154 | 146 | 136 | 138 | 138 | 142 | 138 | 140 | 148 | 144 | 150 | 148 | 140 | 152 |
| 21 | 154 | 180 | 152 | 156 | 170 | 170 | 160 | 156 | 160 | 172 | 162 | 158 | 148 | 164 | 160 | 158 | 152 | 162 |
| Summary: | ECG - PR Interval | | | | | | | | | | | | | | | | | |
| Average | 154 | 155 | 155 | 155 | 154 | 151 | 150 | 149 | 148 | 150 | 151 | 155 | 157 | 158 | 158 | 149 | 151 | 153 |
| Std Dev | 14 | 15 | 14 | 17 | 15 | 17 | 16 | 16 | 15 | 18 | 18 | 12 | 14 | 19 | 16 | 14 | 15 | 13 |
| Max | 174 | 182 | 176 | 194 | 180 | 180 | 178 | 178 | 180 | 184 | 184 | 178 | 182 | 196 | 198 | 176 | 186 | 176 |
| Min | 126 | 130 | 128 | 132 | 128 | 126 | 126 | 124 | 124 | 116 | 120 | 130 | 130 | 114 | 132 | 128 | 124 | 130 |

Dec. 17, 1998

Units: msec

Table 12b-2
ECG - PR Interval

Blank = Not Obtained

| Subj | Day 4 12hr | Day 5 PRE | Day 5 Pre | Day 6 Pre | Day 7 Pre | Day 7 2hr | Day 7 4hr | Day 7 6hr | Day 7 8hr | Day 7 12hr | Day 8 Pre | Day 9 Pre | Day 10 Pre | Day 11 Pre | Day 12 Pre | Day 13 Pre | Day 14 Pre | Day 14 2hr |
|----------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|--------------|---------------|---------------|---------------|---------------|---------------|---------------|
| 01 | 158 | 160 | 154 | | 164 | 160 | 142 | 154 | 158 | 152 | 138 | 150 | 166 | 152 | 164 | 166 | 162 | 146 |
| 02 | 158 | 162 | 140 | 140 | 140 | 162 | 166 | 152 | 140 | 156 | 154 | 160 | 150 | 162 | 168 | 162 | 146 | 168 |
| 03 | 198 | 178 | 148 | 148 | 186 | 182 | 182 | 166 | 166 | 186 | 164 | 176 | 184 | 180 | 166 | 160 | 172 | 156 |
| 04 | 154 | 154 | 156 | 156 | 150 | 150 | 152 | 150 | 144 | 150 | 148 | 140 | 144 | 164 | 155 | 152 | 150 | 148 |
| 05 | 152 | 158 | 164 | 164 | 154 | 158 | 156 | 142 | 148 | 156 | 160 | 152 | 160 | 164 | 154 | 158 | 168 | 154 |
| 06 | 140 | 142 | 136 | 136 | 144 | 134 | 134 | 136 | 116 | 142 | 156 | 144 | 144 | 136 | 138 | 134 | 134 | 128 |
| 07 | 156 | 158 | 156 | 156 | 156 | 164 | 148 | 146 | 148 | 132 | 160 | 132 | 152 | 154 | 132 | 134 | 146 | 140 |
| 08 | 146 | 140 | 166 | 166 | 156 | 152 | 130 | 146 | 152 | 144 | 150 | 138 | 150 | | | | | |
| 09 | 158 | 168 | 174 | 174 | 168 | 150 | 152 | 156 | 154 | 154 | 162 | 162 | 174 | 174 | 174 | 168 | 166 | 158 |
| 10 | 134 | 118 | 140 | 140 | 140 | 142 | 134 | 138 | 142 | 136 | 128 | 146 | 140 | 134 | 136 | 148 | 136 | 140 |
| 11 | 144 | 150 | 146 | 146 | 142 | 140 | 134 | 132 | 134 | 136 | 142 | 146 | 142 | 146 | 138 | 152 | 140 | 148 |
| 12 | 176 | 168 | 178 | 178 | 184 | 178 | 174 | 164 | 168 | 170 | 170 | 178 | 178 | 176 | 174 | 176 | 178 | 184 |
| 13 | 144 | 160 | 156 | 156 | 156 | 150 | 146 | 140 | 146 | 148 | 162 | 160 | 156 | 136 | 164 | 162 | 156 | 148 |
| 14 | 182 | 176 | 180 | 180 | 176 | 178 | 160 | 166 | 174 | 172 | 164 | 158 | 166 | 162 | 176 | 182 | 182 | 184 |
| 15 | 152 | 146 | 150 | 150 | 152 | 148 | 138 | 140 | 144 | 152 | 152 | 154 | 152 | 158 | 154 | 154 | 156 | 154 |
| 16 | 188 | 182 | 184 | 184 | 174 | 190 | 180 | 174 | 192 | 172 | 192 | 184 | 192 | 196 | 184 | 186 | 198 | 192 |
| 17 | | | | | | | | | | | | | | | | | | |
| 18 | 152 | 150 | 160 | 160 | 154 | 154 | 138 | 136 | 140 | 146 | 154 | 154 | 156 | 152 | 158 | 156 | 162 | 154 |
| 19 | 128 | 136 | 134 | 134 | 136 | | 126 | 126 | 130 | 130 | 138 | 134 | 136 | 134 | 130 | 136 | 136 | |
| 20 | 132 | 152 | 142 | 142 | 138 | 136 | 140 | 130 | 136 | 140 | 146 | 146 | 148 | 98 | 148 | 142 | 142 | 146 |
| 21 | 150 | 154 | 176 | 176 | 168 | 170 | 156 | 156 | 146 | 153 | 158 | 166 | 170 | 174 | 166 | 172 | 158 | 174 |
| Summary: | | | | | | | | | | | | | | | | | | |
| Average | 155 | 156 | 157 | 157 | 157 | 158 | 149 | 148 | 149 | 151 | 155 | 154 | 158 | 155 | 157 | 158 | 157 | 157 |
| Std Dev | 18 | 15 | 15 | 15 | 15 | 16 | 16 | 13 | 17 | 15 | 14 | 14 | 15 | 22 | 16 | 15 | 17 | 17 |
| Max | 198 | 182 | 184 | 184 | 186 | 190 | 182 | 174 | 192 | 186 | 192 | 184 | 192 | 196 | 184 | 186 | 198 | 192 |
| Min | 128 | 118 | 134 | 134 | 136 | 134 | 126 | 126 | 116 | 130 | 128 | 132 | 136 | 98 | 130 | 134 | 134 | 128 |

Blank = Not Obtained

Table 12b-3
ECG - PR Interval

Units: msec

| Subj | Day 14 4hr | Day 14 6hr | Day 14 8hr | Day 14 12hr | Day 15 Pre | Day 16 Pre | Day 17 Pre | Day 18 Pre | Day 19 Pre | Day 20 Pre | Day 21 Pre | Day 21 2hr | Day 21 4hr | Day 21 6hr | Day 21 8hr |
|----------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| 01 | 150 | 136 | 150 | 140 | 142 | 148 | 148 | 156 | 146 | 158 | 164 | 160 | 148 | 144 | 150 |
| 02 | 152 | 158 | 152 | 156 | 168 | 166 | 176 | 180 | 168 | 172 | 170 | 176 | 166 | 188 | 170 |
| 03 | 142 | 158 | 178 | 180 | 176 | 162 | 156 | 176 | 190 | 170 | 156 | 154 | 176 | 176 | 176 |
| 04 | 142 | 144 | 146 | 154 | 150 | 142 | 156 | 150 | 144 | 146 | 144 | 150 | 148 | 140 | 148 |
| 05 | 144 | 146 | 154 | 170 | 166 | 156 | 150 | 140 | 150 | 162 | 154 | 146 | 150 | 144 | 150 |
| 06 | 142 | 136 | 142 | 148 | 152 | 136 | 150 | 144 | 136 | 132 | 136 | 146 | 140 | 138 | 138 |
| 07 | 154 | 158 | 150 | 136 | 140 | 156 | 126 | 152 | 136 | 144 | 150 | 152 | 154 | 152 | 160 |
| 08 | | | | | | | | | | | | | | | |
| 09 | 148 | 162 | 164 | 162 | 172 | 174 | 174 | 172 | 172 | 174 | 168 | 168 | 164 | 160 | 152 |
| 10 | 142 | 146 | 142 | 148 | 148 | 146 | 150 | 150 | 150 | 140 | 150 | 146 | 138 | 138 | 140 |
| 11 | 130 | 132 | | 130 | 148 | 146 | 144 | 148 | 148 | 144 | 138 | 138 | 126 | 136 | 138 |
| 12 | 170 | 170 | 178 | 140 | 170 | 178 | 166 | 186 | 186 | 174 | 178 | 174 | 170 | 166 | 176 |
| 13 | 140 | 144 | 142 | 144 | 164 | 162 | 140 | 154 | 160 | 140 | 162 | 134 | 150 | 154 | 144 |
| 14 | 162 | 162 | 162 | 174 | 176 | 174 | 166 | 174 | 168 | 170 | 166 | 158 | 158 | 164 | 174 |
| 15 | 152 | 144 | 150 | 144 | 152 | 144 | 148 | 156 | 154 | 150 | 158 | 156 | 148 | 140 | 150 |
| 16 | 184 | 182 | 100 | 186 | 184 | 184 | 186 | 186 | 188 | 184 | 184 | 186 | 178 | 180 | 182 |
| 17 | | | | | | | | | | | | | | | |
| 18 | 136 | 132 | 136 | 144 | 154 | 152 | 156 | 156 | 156 | 160 | 156 | 146 | 142 | 140 | 140 |
| 19 | | | | | 132 | 136 | 132 | 140 | 136 | 136 | 138 | 126 | 130 | 128 | 136 |
| 20 | 144 | 136 | 134 | 130 | 148 | 146 | 150 | 144 | 146 | 144 | 146 | 146 | 140 | 134 | 134 |
| 21 | 172 | 154 | 170 | 168 | 164 | 180 | 176 | 166 | 184 | 186 | 176 | 176 | 166 | 156 | 172 |
| Summary: | | | | | | | | | | | | | | | |
| Average | 150 | 150 | 150 | 153 | 158 | 157 | 155 | 159 | 159 | 157 | 158 | 155 | 152 | 151 | 154 |
| Std Dev | 14 | 14 | 19 | 17 | 14 | 15 | 16 | 15 | 18 | 17 | 14 | 16 | 15 | 17 | 16 |
| Max | 184 | 182 | 178 | 186 | 184 | 184 | 186 | 186 | 190 | 186 | 184 | 186 | 178 | 188 | 182 |
| Min | 130 | 132 | 100 | 130 | 132 | 136 | 126 | 140 | 136 | 132 | 136 | 126 | 126 | 128 | 134 |

Blank = Not Obtained

Table 12b-4
ECG - PR Interval

Units: msec

| Subj | Day 21 12hr | Day 22 Pre | Day 25 Pre | Day 29 Pre | Day 32 Pre | Day 36 Pre | Day 39 Pre | Day 42 Pre | Day 42 .5hr | Day 42 1hr | Day 42 2hr | Day 42 3hr | Day 42 4hr | Day 42 6hr | Day 42 8hr |
|----------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|
| 01 | 148 | 160 | 172 | 148 | 146 | 148 | 144 | 148 | 158 | 138 | 136 | 144 | 144 | 146 | 142 |
| 02 | 166 | 172 | 202 | 180 | 176 | 152 | 158 | | | | | | | | |
| 03 | 164 | 166 | 160 | 170 | 176 | 178 | 144 | 156 | 162 | 166 | 160 | 138 | 164 | 162 | 164 |
| 04 | 148 | 142 | 152 | 134 | 150 | 146 | | | | | | | | | |
| 05 | 154 | 154 | 152 | | | | | | | | | | | | |
| 06 | 142 | 146 | 150 | 140 | 140 | 144 | 124 | 140 | 128 | 140 | 136 | 140 | 136 | 128 | 120 |
| 07 | 156 | 150 | 156 | 162 | 164 | 166 | 164 | 166 | 162 | 172 | 170 | 166 | 172 | 166 | 156 |
| 08 | | | | | | | | | | | | | | | |
| 09 | 162 | 168 | 152 | 158 | 164 | 146 | 154 | 168 | 160 | 150 | 146 | 144 | 150 | 144 | 148 |
| 10 | 128 | 150 | 142 | 134 | 128 | 140 | 138 | 138 | 140 | 148 | 144 | 142 | 144 | 150 | 136 |
| 11 | 138 | 136 | 132 | 134 | 134 | | 130 | 136 | 144 | 144 | 136 | 132 | 134 | 138 | 142 |
| 12 | 172 | 168 | 162 | 160 | 162 | 170 | 158 | 182 | 178 | 178 | 182 | 182 | 178 | 176 | 174 |
| 13 | 148 | 164 | 152 | 134 | 154 | 158 | 154 | 164 | 160 | 158 | 160 | 166 | 168 | 160 | 162 |
| 14 | 164 | 172 | 166 | 180 | 164 | 158 | 162 | | | | | | | | |
| 15 | 142 | 150 | 144 | 138 | 146 | 140 | 146 | 148 | 146 | 152 | 158 | 148 | 142 | 146 | 164 |
| 16 | 182 | 186 | 176 | 180 | 178 | 174 | 176 | 184 | 180 | 162 | 154 | 188 | 156 | 168 | 170 |
| 17 | | | | | | | | | | | | | | | |
| 18 | 148 | 152 | 134 | 140 | 142 | | | 140 | 138 | 142 | 138 | 136 | 136 | 130 | 134 |
| 19 | 134 | 134 | 126 | 134 | 144 | 128 | 126 | 126 | 126 | 130 | 126 | 120 | 128 | 116 | 122 |
| 20 | 138 | 142 | 140 | 140 | 148 | 140 | 136 | 152 | 144 | 148 | 150 | 148 | 144 | 142 | 140 |
| 21 | 160 | 188 | 156 | 146 | 154 | 148 | 148 | 178 | 172 | 174 | 162 | 170 | 146 | 160 | 156 |
| Summary: | | | | | | | | | | | | | | | |
| Average | 152 | 158 | 154 | 151 | 154 | 152 | 148 | 155 | 153 | 153 | 151 | 151 | 149 | 149 | 149 |
| Std Dev | 14 | 16 | 17 | 17 | 15 | 14 | 15 | 18 | 17 | 14 | 15 | 19 | 15 | 17 | 17 |
| Max | 182 | 188 | 202 | 180 | 178 | 178 | 176 | 184 | 180 | 178 | 182 | 188 | 178 | 176 | 174 |
| Min | 128 | 134 | 126 | 134 | 128 | 128 | 124 | 126 | 126 | 130 | 126 | 120 | 128 | 116 | 120 |

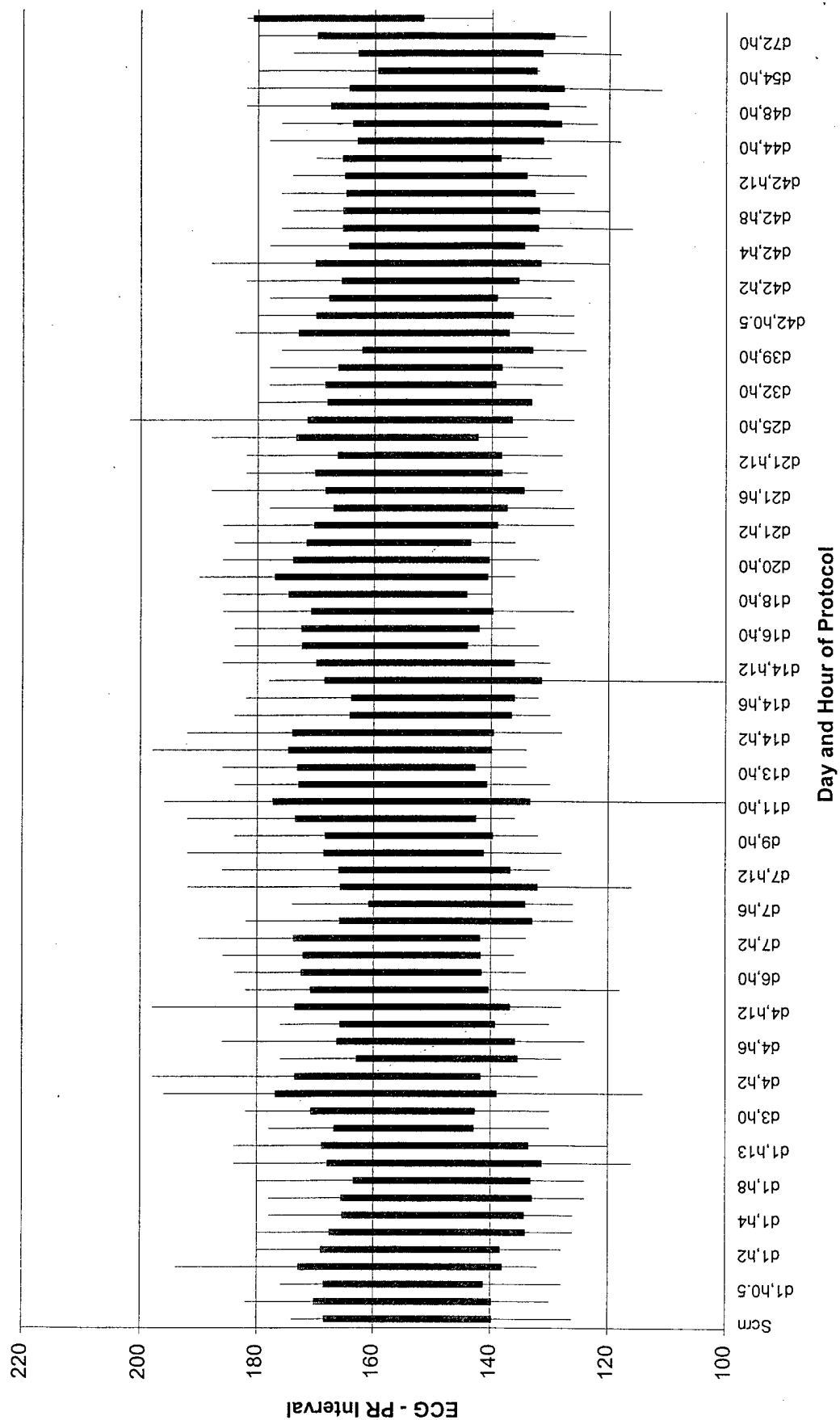
Units: msec

Table 12b-5
ECG - PR Interval

Blank = Not Obtained

| Subj | Day 42 10hr | Day 42 12hr | Day 43 AM | Day 44 AM | Day 45 AM | Day 48 AM | Day 51 AM | Day 54 AM | Day 57 AM | Day 72 AM | Day 180 AM |
|----------|----------------|----------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| 01 | 152 | 154 | 148 | 148 | 154 | 146 | 150 | 158 | 160 | 160 | 160 |
| 02 | | | | | | | | | | | |
| 03 | 164 | 162 | 150 | 158 | 176 | 162 | 154 | 136 | 174 | | 178 |
| 04 | | | | | | | | | | | |
| 05 | | | | | | | | | | | |
| 06 | 128 | 124 | 130 | 134 | 122 | 124 | 111 | 138 | 146 | 128 | |
| 07 | 162 | 164 | 170 | | 168 | 182 | 182 | 154 | 130 | 170 | 182 |
| 08 | | | | | | | | | | | |
| 09 | 148 | 156 | 166 | 162 | | 158 | 142 | 154 | 152 | 172 | 158 |
| 10 | 126 | 148 | 146 | 148 | 130 | 136 | 140 | 152 | | | |
| 11 | 144 | 128 | 146 | 138 | 128 | | | | | | |
| 12 | 176 | 174 | 170 | 166 | 174 | 176 | 168 | 180 | 166 | 166 | 172 |
| 13 | 164 | 162 | 160 | 152 | 152 | 126 | 148 | 142 | 154 | 140 | |
| 14 | | | | | | | | | | | |
| 15 | 152 | 148 | 146 | 144 | 146 | 148 | 142 | 138 | 148 | 140 | 140 |
| 16 | 170 | 170 | 170 | 178 | | | | | | 180 | 174 |
| 17 | | | | | | | | | | | |
| 18 | 132 | 136 | 140 | 126 | 132 | | 138 | 132 | 146 | 132 | |
| 19 | 128 | 130 | 130 | 118 | 136 | 130 | 124 | 132 | 118 | 124 | |
| 20 | 140 | 148 | 148 | 142 | 138 | 146 | 138 | 146 | 138 | 134 | |
| 21 | 146 | 140 | 160 | 146 | 142 | 154 | 162 | 136 | 134 | | |
| Summary: | | | | | | | | | | | |
| Average | 149 | 150 | 152 | 147 | 146 | 149 | 146 | 146 | 147 | 150 | 166 |
| Std Dev | 16 | 16 | 14 | 16 | 18 | 19 | 18 | 14 | 16 | 20 | 15 |
| Max | 176 | 174 | 170 | 178 | 176 | 182 | 182 | 180 | 174 | 180 | 182 |
| Min | 126 | 124 | 130 | 118 | 122 | 124 | 111 | 132 | 118 | 124 | 140 |

Figure 52: SD & Range Charts for ECG - PR Interval



Units: msec

Table 12c-1
ECG - QRS Interval

Blank = Not Obtained

| Subj | Scrn | Day 1 Pre | Day 1 .5hr | Day 1 1hr | Day 1 2hr | Day 1 3hr | Day 1 4hr | Day 1 6hr | Day 1 8hr | Day 1 10hr | Day 1 12hr | Day 2 Pre | Day 3 Pre | Day 4 Pre | Day 4 2hr |
|---------|--------------------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|---------------|--------------|--------------|--------------|--------------|
| 01 | 80 | 86 | 78 | 82 | 82 | 80 | 80 | 82 | 80 | 78 | 78 | 82 | 86 | 80 | 82 |
| 02 | 86 | 84 | 82 | 92 | 86 | 72 | 86 | 82 | 82 | 86 | 80 | 84 | 68 | 74 | 76 |
| 03 | 86 | 84 | 86 | 86 | 84 | 86 | 86 | 84 | 86 | 84 | 86 | 82 | 86 | 88 | 92 |
| 04 | 88 | 84 | 90 | 90 | 90 | 82 | 90 | 88 | 90 | 92 | 84 | 90 | 94 | 96 | 98 |
| 05 | 88 | 80 | 86 | 90 | 82 | 84 | 86 | 78 | 86 | 84 | 86 | 88 | 86 | 84 | 80 |
| 06 | 106 | 106 | 102 | 104 | 104 | 108 | 108 | 110 | 106 | 108 | 106 | 104 | 108 | 104 | 106 |
| 07 | 108 | 106 | 110 | 108 | 100 | 104 | 98 | 104 | 110 | 108 | 110 | 102 | 108 | 102 | 102 |
| 08 | 74 | 86 | 86 | 88 | 94 | 74 | 78 | 72 | 70 | 86 | 80 | 82 | 90 | 86 | 74 |
| 09 | 100 | 100 | 100 | 96 | 98 | | 94 | 98 | 94 | 90 | 94 | 98 | 98 | 98 | 94 |
| 10 | 74 | 72 | 70 | 70 | 72 | 70 | 72 | 72 | 68 | 70 | 72 | 72 | 70 | 74 | 74 |
| 11 | 86 | 80 | 78 | 80 | 78 | 86 | 84 | 84 | 84 | 76 | 78 | 78 | 84 | 82 | 80 |
| 12 | 88 | 92 | 100 | 94 | 100 | 88 | 90 | 90 | 84 | 86 | 92 | 98 | 94 | 104 | 98 |
| 13 | 92 | 84 | 98 | 94 | 94 | 90 | 92 | 88 | 88 | 90 | 88 | 100 | 100 | 92 | 92 |
| 14 | 108 | 100 | 100 | 102 | 98 | 100 | 90 | 100 | 110 | 102 | 102 | 100 | 100 | 84 | 100 |
| 15 | 102 | 104 | 104 | 104 | 100 | 100 | 104 | 94 | 102 | 96 | 102 | 110 | 98 | 104 | 102 |
| 16 | 84 | 82 | 80 | 82 | 86 | 84 | 84 | 90 | 88 | 86 | 88 | 82 | 94 | 86 | 84 |
| 17 | 84 | 88 | 88 | 94 | 94 | 96 | 96 | 96 | | | | | | | |
| 18 | 86 | 90 | 88 | 86 | 90 | 90 | 86 | 90 | 86 | 88 | 88 | 90 | 94 | 90 | 90 |
| 19 | 92 | 82 | 88 | 86 | 84 | 84 | 84 | 84 | 76 | 78 | 88 | 80 | 82 | 76 | 68 |
| 20 | | 100 | 108 | 92 | 94 | 94 | 98 | 88 | 90 | 90 | 88 | 100 | 86 | 94 | 106 |
| 21 | 96 | 102 | 104 | 104 | 104 | 102 | 104 | 100 | 102 | 100 | 100 | 100 | 108 | 100 | 98 |
| Summary | ECG - QRS Interval, msec | | | | | | | | | | | | | | |
| Average | 90 | 90 | 92 | 92 | 91 | 89 | 90 | 89 | 89 | 89 | 90 | 91 | 92 | 90 | 90 |
| Std Dev | 10 | 10 | 11 | 09 | 09 | 11 | 09 | 10 | 12 | 10 | 10 | 11 | 11 | 10 | 12 |
| Max | 108 | 106 | 110 | 108 | 104 | 108 | 108 | 110 | 110 | 108 | 110 | 110 | 108 | 104 | 106 |
| Min | 74 | 72 | 70 | 70 | 72 | 70 | 72 | 72 | 68 | 70 | 72 | 72 | 68 | 74 | 68 |

Units: msec

Table 12c-2
ECG- QRS Interval

Blank = Not Obtained

| Subj | Day 4 4hr | Day 4 6hr | Day 4 8hr | Day 4 12hr | Day 5 PRE | Day 6 Pre | Day 7 Pre | Day 7 2hr | Day 7 4hr | Day 7 6hr | Day 7 8hr | Day 7 12hr | Day 8 Pre | Day 9 Pre | Day 10 Pre |
|---------|--------------|--------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|--------------|---------------|
| 01 | 82 | 80 | 80 | 82 | 82 | 82 | 78 | 82 | 80 | 80 | 96 | 84 | 84 | 80 | 84 |
| 02 | 78 | 70 | 74 | 72 | 68 | 84 | 74 | 76 | 82 | 86 | 86 | 86 | 94 | 80 | 72 |
| 03 | 90 | 90 | 90 | 84 | 84 | 78 | 86 | 84 | 88 | 86 | 84 | 86 | 84 | 82 | 80 |
| 04 | 96 | 92 | 92 | 92 | 92 | 96 | 90 | 90 | 92 | 94 | 90 | 78 | 92 | 84 | 92 |
| 05 | 74 | 82 | 80 | 82 | 78 | 86 | 78 | 86 | 86 | 84 | 74 | 88 | 82 | 78 | 78 |
| 06 | 106 | 106 | 106 | 108 | 110 | 110 | 110 | 108 | 104 | 108 | 106 | 110 | 106 | 106 | 110 |
| 07 | 102 | 100 | 104 | 98 | 98 | 96 | 110 | 110 | 110 | 114 | 110 | 108 | 98 | 110 | 106 |
| 08 | 90 | 86 | 84 | 76 | 84 | 86 | 86 | 86 | 90 | 84 | 80 | 84 | 70 | 84 | 82 |
| 09 | 96 | 94 | 94 | 90 | 98 | 100 | 100 | 96 | 94 | 96 | 94 | 98 | 100 | 106 | 100 |
| 10 | 74 | 72 | 76 | 72 | 76 | 74 | 74 | 74 | 74 | 72 | 74 | 74 | 74 | 74 | 74 |
| 11 | 80 | 82 | 84 | 84 | 84 | 84 | 78 | 78 | 76 | 82 | 80 | 84 | 76 | 76 | 84 |
| 12 | 100 | 90 | 86 | 90 | 92 | 90 | 100 | 88 | 86 | 96 | 88 | 100 | 86 | 88 | 90 |
| 13 | 88 | 96 | 88 | 88 | 92 | 88 | 94 | 88 | 88 | 86 | 88 | 86 | 94 | 98 | 96 |
| 14 | 100 | 94 | 100 | 100 | 102 | 100 | 88 | 104 | 90 | 100 | 90 | 100 | 92 | 88 | 92 |
| 15 | 104 | 102 | 100 | 100 | 96 | 102 | 98 | 102 | 98 | 100 | 98 | 104 | 104 | 104 | 104 |
| 16 | 86 | 84 | 86 | 80 | 86 | 94 | 90 | 88 | 88 | 86 | 66 | 80 | 88 | 88 | 88 |
| 17 | | | | | | | | | | | | | | | |
| 18 | 88 | 86 | 90 | 92 | 92 | 92 | 90 | 90 | 86 | 98 | 86 | 90 | 94 | 94 | 102 |
| 19 | 78 | 76 | 74 | 78 | 86 | 70 | 80 | | 84 | 82 | 86 | 80 | 82 | 84 | 92 |
| 20 | 94 | 94 | 104 | 94 | 102 | 104 | 100 | 94 | 92 | 94 | 96 | 82 | 108 | 102 | 102 |
| 21 | 100 | 98 | 96 | 98 | 100 | 100 | 104 | 102 | 98 | 102 | 100 | 104 | 108 | 108 | 102 |
| Summary | | | | | | | | | | | | | | | |
| Average | 90 | 89 | 89 | 88 | 90 | 91 | 90 | 91 | 89 | 92 | 89 | 90 | 91 | 91 | 92 |
| Std Dev | 10 | 10 | 10 | 10 | 10 | 10 | 11 | 11 | 09 | 10 | 11 | 11 | 11 | 12 | 11 |
| Max | 106 | 106 | 106 | 108 | 110 | 110 | 110 | 110 | 110 | 114 | 110 | 110 | 108 | 110 | 110 |
| Min | 74 | 70 | 74 | 72 | 68 | 70 | 74 | 74 | 74 | 72 | 66 | 74 | 70 | 74 | 72 |

Units: msec

Table 12c-3
ECG-QRS Interval

Blank = Not Obtained

| Subj | Day 11 Pre | Day 12 Pre | Day 13 Pre | Day 14 Pre | Day 14 2hr | Day 14 4hr | Day 14 6hr | Day 14 8hr | Day 14 12hr | Day 15 Pre | Day 16 Pre | Day 17 Pre | Day 18 Pre |
|---------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|
| 01 | 84 | 84 | 88 | 84 | 86 | 98 | 86 | 96 | 86 | 84 | 82 | 86 | 84 |
| 02 | 82 | 72 | 86 | 82 | 86 | 86 | 86 | 86 | 88 | 78 | 86 | 70 | 82 |
| 03 | 76 | 84 | 84 | 86 | 84 | 78 | 84 | 86 | 86 | 80 | 78 | 78 | 84 |
| 04 | 92 | 82 | 90 | 80 | 80 | 92 | 92 | 80 | 80 | 76 | 92 | 86 | 90 |
| 05 | 88 | 78 | 78 | 70 | 82 | 76 | 80 | 76 | 76 | 80 | 74 | 78 | 92 |
| 06 | 106 | 106 | 106 | 100 | 104 | 104 | 106 | 102 | 108 | 104 | 106 | 106 | 108 |
| 07 | 106 | 98 | 94 | 106 | 108 | 108 | 108 | 112 | 110 | 106 | 106 | 106 | 96 |
| 08 | | | | | | | | | | | | | |
| 09 | 100 | 102 | 102 | 102 | 96 | 90 | 92 | 96 | 96 | 98 | 98 | 98 | 104 |
| 10 | 74 | 74 | 74 | 76 | 76 | 76 | 74 | 74 | 74 | 74 | 74 | 74 | 74 |
| 11 | 78 | 74 | 84 | 82 | 84 | 82 | 82 | 78 | 76 | 82 | 84 | 84 | 82 |
| 12 | 94 | 88 | 96 | 92 | 96 | 96 | 94 | 92 | 76 | 92 | 94 | 102 | 92 |
| 13 | 98 | 96 | 92 | 102 | 98 | 92 | 94 | 86 | 94 | 96 | 98 | 94 | 96 |
| 14 | 100 | 92 | 100 | 90 | 100 | 90 | 102 | 98 | 102 | 84 | 102 | 92 | 102 |
| 15 | 104 | 104 | 106 | 102 | 100 | 106 | 104 | 102 | 108 | 102 | 106 | 104 | 102 |
| 16 | 88 | 90 | 84 | 90 | 90 | 90 | 86 | 88 | 84 | 88 | 84 | 88 | 86 |
| 17 | | | | | | | | | | | | | |
| 18 | 92 | 90 | 92 | 94 | 92 | 92 | 86 | 86 | 90 | 94 | 94 | 94 | 90 |
| 19 | 86 | 84 | 74 | 72 | | | | | | 76 | 80 | 74 | 86 |
| 20 | 108 | 78 | 80 | 102 | 82 | 86 | 98 | 102 | 88 | 90 | 78 | 100 | 94 |
| 21 | 98 | 102 | 98 | 100 | 102 | 100 | 98 | 98 | 96 | 100 | 104 | 106 | 102 |
| Summary | | | | | | | | | | | | | |
| Average | 92 | 88 | 90 | 90 | 91 | 91 | 92 | 91 | 90 | 89 | 91 | 91 | 92 |
| Std Dev | 11 | 11 | 10 | 11 | 09 | 10 | 10 | 10 | 12 | 10 | 11 | 12 | 09 |
| Max | 108 | 106 | 106 | 106 | 108 | 108 | 108 | 112 | 110 | 106 | 106 | 106 | 108 |
| Min | 74 | 72 | 74 | 70 | 76 | 76 | 74 | 74 | 74 | 74 | 74 | 70 | 74 |

Units: msec

Table 12c-4
ECG- QRS Interval

Blank = Not Obtained

| Subj | Day 19 Pre | Day 20 Pre | Day 21 Pre | Day 21 2hr | Day 21 4hr | Day 21 6hr | Day 21 8hr | Day 21 12hr | Day 22 Pre | Day 25 Pre | Day 29 Pre | Day 32 Pre | Day 36 Pre |
|---------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|
| 01 | 76 | 84 | 82 | 82 | 86 | 84 | 84 | 82 | 84 | 80 | 88 | 84 | 84 |
| 02 | 70 | 84 | 88 | 72 | 82 | 92 | 86 | 84 | 88 | 70 | 80 | | 90 |
| 03 | 80 | 84 | 82 | 90 | 82 | 90 | 82 | 82 | 82 | 82 | 88 | 86 | 86 |
| 04 | 90 | 88 | 90 | 90 | 92 | 82 | 96 | 98 | 80 | 90 | 90 | 90 | 88 |
| 05 | 86 | 78 | 78 | 76 | 74 | 74 | 76 | 76 | 80 | 80 | | | |
| 06 | 106 | 108 | 106 | 106 | 110 | 106 | 104 | 108 | 106 | 104 | 106 | 108 | 106 |
| 07 | 98 | 100 | 96 | 98 | 102 | 96 | 102 | 100 | 106 | 104 | 106 | 110 | 106 |
| 08 | | | | | | | | | | | | | |
| 09 | 102 | 102 | 96 | 98 | 96 | 98 | 96 | 90 | 98 | 100 | 94 | 96 | 102 |
| 10 | 74 | 72 | 74 | 72 | 72 | 74 | 72 | 72 | 72 | 72 | 74 | 74 | 74 |
| 11 | 84 | 84 | 86 | 82 | 80 | 80 | 80 | 74 | 80 | 86 | 76 | 86 | |
| 12 | 88 | 96 | 82 | 96 | 88 | 84 | 90 | 90 | 90 | 82 | 86 | 94 | 88 |
| 13 | 94 | 100 | 102 | 84 | 86 | 86 | 88 | 86 | 94 | 88 | 104 | 92 | 96 |
| 14 | 90 | 100 | 88 | 100 | 92 | 100 | 92 | 84 | 92 | 98 | 90 | 106 | 100 |
| 15 | 104 | 106 | 102 | 104 | 102 | 100 | 102 | 100 | 106 | 104 | 102 | 100 | 104 |
| 16 | 88 | 90 | 86 | 84 | 88 | 84 | 82 | 88 | 86 | 84 | 86 | 92 | 84 |
| 17 | | | | | | | | | | | | | |
| 18 | 92 | 92 | 92 | 94 | 90 | 86 | 88 | 94 | 94 | 90 | 84 | 94 | |
| 19 | 84 | 90 | 76 | 74 | 80 | 80 | 72 | 80 | 74 | 88 | 76 | 80 | 88 |
| 20 | 102 | 96 | 76 | 102 | 96 | 96 | 92 | 92 | 80 | 94 | 94 | 90 | 86 |
| 21 | 108 | 106 | 100 | 104 | 100 | 100 | 100 | 100 | 102 | 102 | 102 | 106 | 90 |
| Summary | | | | | | | | | | | | | |
| Average | 90 | 93 | 89 | 90 | 89 | 89 | 89 | 88 | 89 | 89 | 90 | 93 | 92 |
| Std Dev | 11 | 10 | 10 | 11 | 10 | 09 | 10 | 10 | 11 | 11 | 10 | 10 | 09 |
| Max | 108 | 108 | 106 | 106 | 110 | 106 | 104 | 108 | 106 | 104 | 106 | 110 | 106 |
| Min | 70 | 72 | 74 | 72 | 72 | 74 | 72 | 72 | 72 | 70 | 74 | 74 | 74 |

Units: msec

Table 12c-5
ECG-QRS Interval

Blank = Not Obtained

| Subj | Day 39 Pre | Day 42 Pre | Day 42 .5hr | Day 42 1hr | Day 42 2hr | Day 42 3hr | Day 42 4hr | Day 42 6hr | Day 42 8hr | Day 42 10hr | Day 42 12hr | Day 43 AM | Day 44 AM |
|---------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|--------------|--------------|
| 01 | 82 | 94 | 94 | 88 | 78 | 82 | 80 | 82 | 84 | 80 | 84 | 100 | 86 |
| 02 | 90 | | | | | | | | | | | | |
| 03 | 84 | 86 | 84 | 82 | 86 | 82 | 84 | 94 | 82 | 86 | 84 | 84 | 92 |
| 04 | | | | | | | | | | | | | |
| 05 | | | | | | | | | | | | | |
| 06 | 108 | 106 | 104 | 106 | 106 | 106 | 104 | 112 | 112 | 112 | 114 | 108 | 108 |
| 07 | 110 | 112 | 112 | 112 | 114 | 114 | 116 | 114 | 110 | 116 | 112 | 112 | |
| 08 | | | | | | | | | | | | | |
| 09 | 98 | 100 | 90 | 98 | 90 | 92 | 96 | 86 | 94 | 96 | 98 | 102 | 94 |
| 10 | 74 | 72 | 74 | 72 | 82 | 72 | 74 | 72 | 70 | 74 | 72 | 74 | 74 |
| 11 | 84 | 84 | 84 | 84 | 78 | 84 | 76 | 86 | 86 | 82 | 78 | 76 | 76 |
| 12 | 96 | 88 | 90 | 86 | 88 | 92 | 92 | 86 | 86 | 92 | 88 | 92 | 96 |
| 13 | 98 | 96 | 108 | 100 | 90 | 94 | 94 | 100 | 100 | 88 | 90 | 92 | 94 |
| 14 | 84 | | | | | | | | | | | | |
| 15 | 104 | 100 | 96 | 100 | 106 | 104 | 108 | 100 | 104 | 96 | 104 | 108 | 102 |
| 16 | 84 | 90 | 88 | 78 | 86 | 74 | 82 | 84 | 78 | 86 | 80 | 84 | 84 |
| 17 | | | | | | | | | | | | | |
| 18 | | 94 | 92 | 90 | 94 | 94 | 94 | 84 | 90 | 88 | 84 | 92 | 98 |
| 19 | 78 | 80 | 72 | 80 | 72 | 82 | 78 | 74 | 78 | 74 | 74 | 78 | 80 |
| 20 | 96 | 84 | 86 | 80 | 86 | 86 | 86 | 86 | 84 | 82 | 86 | 84 | 86 |
| 21 | 96 | 108 | 106 | 106 | 106 | 102 | 108 | 104 | 106 | 106 | 104 | 104 | 106 |
| Summary | | | | | | | | | | | | | |
| Average | 92 | 93 | 92 | 91 | 91 | 91 | 91 | 91 | 91 | 91 | 90 | 93 | 91 |
| Std Dev | 11 | 11 | 12 | 12 | 12 | 12 | 13 | 13 | 13 | 13 | 13 | 12 | 11 |
| Max | 110 | 112 | 112 | 112 | 114 | 114 | 116 | 114 | 112 | 116 | 114 | 112 | 108 |
| Min | 74 | 72 | 72 | 72 | 72 | 72 | 74 | 72 | 70 | 74 | 72 | 74 | 74 |

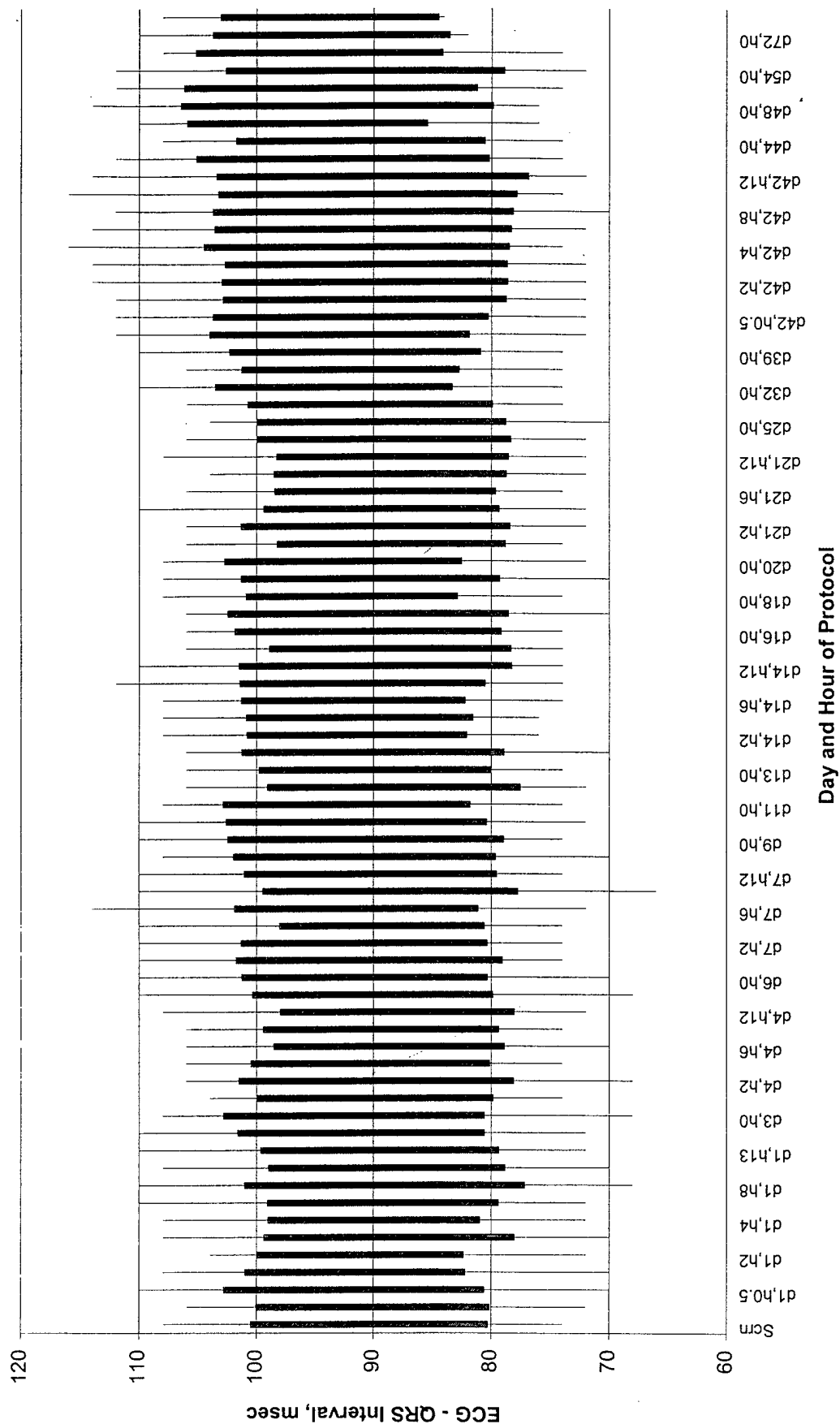
Units: msec

Table 12c-6
ECG- QRS Interval

Blank = Not Obtained

| Subj | Day 45 AM | Day 48 AM | Day 51 AM | Day 54 AM | Day 57 AM | Day 72 AM | Day 180 AM |
|---------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| 01 | 92 | 80 | 84 | 84 | 86 | 98 | 84 |
| 02 | | | | | | | |
| 03 | 94 | 80 | 82 | 80 | 86 | | 86 |
| 04 | | | | | | | |
| 05 | | | | | | | |
| 06 | 110 | 114 | 110 | 112 | 106 | 110 | 104 |
| 07 | 108 | 108 | 112 | 108 | 106 | 108 | 108 |
| 08 | | | | | | | |
| 09 | | 94 | 102 | 94 | 96 | 94 | 90 |
| 10 | | 76 | 74 | 72 | | | |
| 11 | 84 | | | | | | |
| 12 | 92 | 86 | 88 | 86 | 88 | 88 | 90 |
| 13 | 92 | 90 | 90 | 88 | 88 | 96 | 94 |
| 14 | | | | | | | |
| 15 | 104 | 104 | 102 | 98 | 100 | 102 | 104 |
| 16 | | | | | | 84 | 84 |
| 17 | | | | | | | |
| 18 | 92 | | 94 | 92 | 94 | 86 | |
| 19 | 76 | 78 | 80 | 74 | 74 | 82 | |
| 20 | 96 | 102 | 90 | 96 | 108 | 82 | |
| 21 | 108 | 106 | 110 | 96 | 104 | | |
| Summary | | | | | | | |
| Average | 96 | 93 | 94 | 91 | 95 | 94 | 94 |
| Std Dev | 10 | 13 | 12 | 12 | 11 | 10 | 09 |
| Max | 110 | 114 | 112 | 112 | 108 | 110 | 108 |
| Min | 76 | 76 | 74 | 72 | 74 | 82 | 84 |

Figure 53: SD & Range Charts for ECG - QRS Interval, msec



Blank = Not Obtained

Table 12d-1
ECG-QTc Interval

Units: msec

| Subj | Scrn | Day 1 Pre | Day 1 .5hr | Day 1 1hr | Day 1 2hr | Day 1 3hr | Day 1 4hr | Day 1 6hr | Day 1 8hr | Day 1 10hr | Day 1 12hr | Day 2 Pre | Day 3 Pre | Day 4 Pre | Day 4 2hr |
|---------|--------------------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|---------------|--------------|--------------|--------------|--------------|
| 01 | 397 | 399 | 397 | 403 | 384 | 371 | 407 | 396 | 393 | 402 | 391 | 381 | 392 | 389 | 386 |
| 02 | 413 | 404 | 409 | 405 | 387 | 419 | 410 | 382 | 442 | 411 | 414 | 399 | 408 | 393 | 413 |
| 03 | 380 | 402 | 379 | 375 | 410 | 412 | 401 | 403 | 406 | 392 | 384 | 388 | 393 | 392 | 407 |
| 04 | 406 | 383 | 389 | 373 | 376 | 398 | 395 | 395 | 396 | 389 | 397 | 388 | 401 | 411 | 423 |
| 05 | 372 | 390 | 376 | 394 | 407 | 372 | 373 | 387 | 383 | 404 | 404 | 388 | 383 | 403 | 397 |
| 06 | 385 | 382 | 368 | 356 | 347 | 369 | 363 | 345 | 353 | 386 | 358 | 341 | 348 | 352 | 348 |
| 07 | 412 | 398 | 378 | 403 | 420 | 409 | 408 | 364 | 368 | 396 | 406 | 388 | 391 | 410 | 388 |
| 08 | 383 | 372 | 371 | 380 | 380 | 366 | 371 | 401 | 383 | 379 | 383 | 383 | 384 | 377 | 372 |
| 09 | 379 | 395 | 374 | 375 | 359 | | 386 | 401 | 391 | 381 | 391 | 368 | 393 | 416 | 384 |
| 10 | 400 | 398 | 392 | 400 | 402 | 409 | 399 | 395 | 396 | 406 | 400 | 377 | 404 | 404 | 413 |
| 11 | 418 | 412 | 421 | 414 | 409 | 455 | 474 | 414 | 414 | 415 | 416 | 423 | 444 | 435 | 425 |
| 12 | 394 | 384 | 376 | 399 | 387 | 399 | 396 | 367 | 389 | 378 | 364 | 379 | 390 | 360 | 363 |
| 13 | 394 | 383 | 397 | 395 | 390 | 394 | 390 | 392 | 393 | 389 | 389 | 391 | 373 | 377 | 395 |
| 14 | 408 | 403 | 406 | 399 | 421 | 416 | 389 | 385 | 426 | 419 | 426 | 420 | 403 | 408 | 412 |
| 15 | 389 | 401 | 388 | 349 | 395 | 374 | 395 | 397 | 392 | 388 | 388 | 399 | 405 | 381 | 416 |
| 16 | 399 | 380 | 396 | 393 | 390 | 400 | 400 | 394 | 374 | 400 | 400 | 392 | 382 | 399 | 395 |
| 17 | 409 | 360 | 409 | 341 | 349 | 346 | 359 | 346 | | | | | | | |
| 18 | 417 | 403 | 394 | 400 | 409 | 403 | 403 | 402 | 403 | 409 | 402 | 409 | 411 | 416 | 412 |
| 19 | 418 | 395 | 377 | 366 | 389 | 404 | 418 | 402 | 402 | 405 | 404 | 402 | 422 | 410 | 404 |
| 20 | | 422 | 392 | 415 | 404 | 402 | 402 | 398 | 398 | 392 | 402 | 438 | 383 | 397 | 422 |
| 21 | 401 | 406 | 403 | 412 | 408 | 409 | 423 | 405 | 406 | 408 | 409 | 408 | 409 | 418 | 422 |
| | | | | | | | | | | | | | | | |
| Summary | ECG - QTc Interval, msec | | | | | | | | | | | | | | |
| Average | 399 | 394 | 390 | 388 | 392 | 396 | 398 | 389 | 395 | 397 | 396 | 393 | 396 | 397 | 400 |
| Std Dev | 14 | 14 | 14 | 21 | 21 | 24 | 24 | 19 | 19 | 12 | 16 | 21 | 20 | 20 | 21 |
| Max | 418 | 422 | 421 | 415 | 421 | 455 | 474 | 414 | 442 | 419 | 426 | 438 | 444 | 435 | 425 |
| Min | 372 | 360 | 368 | 341 | 347 | 346 | 359 | 345 | 353 | 378 | 358 | 341 | 348 | 352 | 348 |

Units: msec

Table 12d-2
ECG-QTc Interval

Blank = Not Obtained

| Subj | Day 4 4hr | Day 4 6hr | Day 4 8hr | Day 4 12hr | Day 5 PRE | Day 6 Pre | Day 7 Pre | Day 7 2hr | Day 7 4hr | Day 7 6hr | Day 7 8hr | Day 7 12hr | Day 8 Pre | Day 9 Pre | Day 10 Pre |
|---------|--------------|--------------|--------------|---------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|--------------|--------------|---------------|
| 01 | 398 | 409 | 382 | 399 | 375 | 393 | 369 | 411 | 402 | 399 | 389 | 403 | 405 | 398 | 403 |
| 02 | 408 | 417 | 413 | 413 | 406 | 412 | 409 | 401 | 408 | 419 | 507 | 420 | 425 | 419 | 406 |
| 03 | 406 | 400 | 404 | 402 | 380 | 390 | 401 | 414 | 403 | 404 | 404 | 407 | 401 | 383 | 404 |
| 04 | 398 | 398 | 417 | 404 | 399 | 411 | 406 | 398 | 402 | 396 | 400 | 402 | 398 | 400 | 398 |
| 05 | 381 | 410 | 402 | 391 | 382 | 415 | 411 | 374 | 395 | 399 | 369 | 413 | 400 | 389 | 396 |
| 06 | 379 | 371 | 385 | 385 | 349 | 357 | 391 | 355 | 374 | 388 | 387 | 382 | 390 | 356 | 364 |
| 07 | 423 | 414 | 413 | 417 | 403 | 410 | 414 | 398 | 435 | 419 | 411 | 453 | 418 | 418 | 414 |
| 08 | 388 | 404 | 382 | 407 | 385 | 385 | 387 | 398 | 409 | 394 | 398 | 384 | 402 | 417 | 390 |
| 09 | 403 | 391 | 385 | 409 | 384 | 397 | 372 | 358 | 389 | 407 | 396 | 406 | 399 | 428 | 411 |
| 10 | 412 | 405 | 412 | 414 | 412 | 409 | 410 | 419 | 405 | 399 | 418 | 406 | 414 | 414 | 438 |
| 11 | 437 | 416 | 448 | 439 | 439 | 444 | 421 | 434 | 424 | 429 | 437 | 410 | 424 | 423 | 430 |
| 12 | 391 | 393 | 382 | 361 | 396 | 356 | 382 | 399 | 391 | 394 | 378 | 392 | 394 | 400 | 403 |
| 13 | 394 | 402 | 380 | 394 | 384 | 409 | 407 | 403 | 396 | 374 | 401 | 399 | 411 | 394 | 396 |
| 14 | 410 | 403 | 407 | 398 | 404 | 419 | 412 | 413 | 416 | 412 | 420 | 420 | 413 | 413 | 424 |
| 15 | 396 | 383 | 401 | 381 | 388 | 404 | 398 | 383 | 395 | 365 | 394 | 371 | 397 | 396 | 401 |
| 16 | 396 | 399 | 401 | 401 | 403 | 404 | 405 | 404 | 401 | 400 | 399 | 407 | 406 | 405 | 400 |
| 17 | | | | | | | | | | | | | | | |
| 18 | 413 | 441 | 411 | 415 | 422 | 415 | 421 | 410 | 438 | 435 | 422 | 421 | 418 | 451 | 422 |
| 19 | 409 | 410 | 418 | 404 | 404 | 404 | 403 | | 403 | 413 | 421 | 408 | 403 | 409 | 406 |
| 20 | 404 | 403 | 413 | 416 | 378 | 411 | 407 | 411 | 413 | 408 | 400 | 405 | 411 | 407 | 413 |
| 21 | 404 | 420 | 402 | 406 | 411 | 404 | 417 | 411 | 420 | 408 | 421 | 426 | 409 | 416 | 407 |
| Summary | | | | | | | | | | | | | | | |
| Average | 403 | 404 | 403 | 403 | 395 | 402 | 402 | 400 | 406 | 403 | 409 | 407 | 407 | 407 | 406 |
| Std Dev | 14 | 15 | 17 | 16 | 20 | 20 | 15 | 20 | 15 | 17 | 28 | 18 | 10 | 19 | 16 |
| Max | 437 | 441 | 448 | 439 | 439 | 444 | 421 | 434 | 438 | 435 | 507 | 453 | 425 | 451 | 438 |
| Min | 379 | 371 | 380 | 361 | 349 | 356 | 369 | 355 | 374 | 365 | 369 | 371 | 390 | 356 | 364 |

Units: msec

Table 12d-3
ECG-QTc Interval

Blank = Not Obtained

| Subj | Day 11 Pre | Day 12 Pre | Day 13 Pre | Day 14 Pre | Day 14 2hr | Day 14 4hr | Day 14 6hr | Day 14 8hr | Day 14 12hr | Day 15 Pre | Day 16 Pre | Day 17 Pre | Day 18 Pre |
|---------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|
| 01 | 389 | 389 | 404 | 396 | 404 | 404 | 402 | 406 | 404 | 372 | 393 | 385 | 401 |
| 02 | 428 | 433 | 418 | 413 | 464 | 416 | 450 | 422 | 452 | 434 | 422 | 411 | 428 |
| 03 | 405 | 402 | 388 | 405 | 402 | 382 | 403 | 403 | 408 | 386 | 410 | 399 | 410 |
| 04 | 401 | 400 | 400 | 401 | 402 | 398 | 404 | 399 | 402 | 399 | 402 | 396 | 403 |
| 05 | 405 | 403 | 416 | 417 | 395 | 396 | 409 | 370 | 401 | 391 | 387 | 394 | 416 |
| 06 | 360 | 359 | 359 | 346 | 350 | 382 | 374 | 389 | 381 | 377 | 387 | 369 | 388 |
| 07 | 401 | 423 | 412 | 408 | 407 | 446 | 440 | 485 | 424 | 408 | 418 | 403 | 411 |
| 08 | | | | | | | | | | | | | |
| 09 | 391 | 413 | 423 | 398 | 412 | 406 | 393 | 411 | 417 | 383 | 407 | 403 | 416 |
| 10 | 420 | 418 | 406 | 402 | 406 | 442 | 439 | 450 | 420 | 414 | 426 | 411 | 431 |
| 11 | 427 | 412 | 407 | 438 | 409 | 447 | 436 | 439 | 452 | 448 | 446 | 424 | 437 |
| 12 | 404 | 401 | 401 | 394 | 392 | 375 | 401 | 391 | 396 | 395 | 399 | 369 | 397 |
| 13 | 379 | 403 | 391 | 389 | 398 | 408 | 371 | 438 | 410 | 403 | 407 | 395 | 417 |
| 14 | 428 | 421 | 418 | 413 | 419 | 413 | 413 | 405 | 417 | 407 | 412 | 422 | 401 |
| 15 | 404 | 388 | 401 | 396 | 398 | 430 | 410 | 409 | 398 | 400 | 385 | 375 | 403 |
| 16 | 408 | 397 | 411 | 402 | 416 | 403 | 404 | 403 | 400 | 399 | 402 | 412 | 396 |
| 17 | | | | | | | | | | | | | |
| 18 | 416 | 419 | 440 | 430 | 425 | 428 | 425 | 420 | 428 | 426 | 437 | 424 | 431 |
| 19 | 407 | 408 | 393 | 416 | | | | | | 403 | 399 | 415 | 405 |
| 20 | 409 | 425 | 415 | 411 | 405 | 410 | 410 | 426 | 424 | 409 | 417 | 411 | 411 |
| 21 | 416 | 419 | 409 | 400 | 411 | 406 | 416 | 403 | 410 | 415 | 419 | 405 | 412 |
| Summary | | | | | | | | | | | | | |
| Average | 405 | 407 | 406 | 404 | 406 | 411 | 411 | 415 | 414 | 404 | 409 | 401 | 411 |
| Std Dev | 17 | 17 | 17 | 19 | 21 | 21 | 21 | 26 | 18 | 19 | 17 | 17 | 13 |
| Max | 428 | 433 | 440 | 438 | 464 | 447 | 450 | 485 | 452 | 448 | 446 | 424 | 437 |
| Min | 360 | 359 | 359 | 346 | 350 | 375 | 371 | 370 | 381 | 372 | 385 | 369 | 388 |

Units: msec

Table 12d-4
ECG-QTc Interval

Blank = Not Obtained

| Subj | Day 19 Pre | Day 20 Pre | Day 21 Pre | Day 21 2hr | Day 21 4hr | Day 21 6hr | Day 21 8hr | Day 21 12hr | Day 22 Pre | Day 25 Pre | Day 29 Pre | Day 32 Pre | Day 36 Pre |
|---------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|
| 01 | 427 | 404 | 400 | 396 | 409 | 400 | 421 | 402 | 423 | 416 | 450 | 449 | 407 |
| 02 | 434 | 432 | 428 | 393 | 419 | 466 | 505 | 450 | 455 | 462 | 432 | 479 | 441 |
| 03 | 408 | 389 | 409 | 387 | 390 | 409 | 406 | 418 | 404 | 405 | 408 | 412 | 389 |
| 04 | 399 | 402 | 402 | 402 | 409 | 406 | 411 | 408 | 427 | 420 | 414 | 404 | 402 |
| 05 | 407 | 400 | 390 | 385 | 403 | 380 | 415 | 389 | 395 | 395 | | | |
| 06 | 380 | 368 | 360 | 394 | 393 | 389 | 391 | 388 | 382 | 396 | 390 | 394 | 370 |
| 07 | 420 | 412 | 440 | 432 | 423 | 420 | 432 | 431 | 424 | 481 | 440 | 456 | 405 |
| 08 | | | | | | | | | | | | | |
| 09 | 374 | 421 | 368 | 427 | 427 | 440 | 433 | 416 | 438 | 438 | 410 | 409 | 432 |
| 10 | 440 | 420 | 415 | 403 | 433 | 451 | 429 | 446 | 416 | 405 | 432 | 414 | 377 |
| 11 | 431 | 458 | 451 | 454 | 441 | 450 | 483 | 438 | 440 | 474 | 441 | 438 | |
| 12 | 393 | 390 | 382 | 390 | 400 | 395 | 393 | 399 | 393 | 402 | 401 | 406 | 405 |
| 13 | 389 | 374 | 377 | 393 | 405 | 395 | 399 | 398 | 394 | 420 | 420 | 412 | 409 |
| 14 | 422 | 421 | 421 | 415 | 413 | 420 | 414 | 421 | 416 | 444 | 450 | 430 | 448 |
| 15 | 409 | 397 | 392 | 401 | 435 | 416 | 409 | 403 | 394 | 423 | 418 | 402 | 407 |
| 16 | 403 | 411 | 404 | 391 | 421 | 414 | 410 | 411 | 400 | 420 | 426 | 434 | 424 |
| 17 | | | | | | | | | | | | | |
| 18 | 452 | 432 | 426 | 414 | 437 | 446 | 428 | 428 | 431 | 450 | 426 | 453 | |
| 19 | 411 | 408 | 396 | 404 | 407 | 405 | 405 | 405 | 410 | 408 | 411 | 442 | 420 |
| 20 | 402 | 409 | 410 | 411 | 417 | 417 | 432 | 416 | 424 | 415 | 448 | 426 | 427 |
| 21 | 426 | 413 | 411 | 406 | 407 | 397 | 407 | 429 | 409 | 409 | 413 | 415 | 417 |
| Summary | | | | | | | | | | | | | |
| Average | 412 | 408 | 404 | 405 | 415 | 417 | 422 | 416 | 414 | 425 | 424 | 426 | 411 |
| Std Dev | 21 | 21 | 24 | 17 | 15 | 24 | 29 | 18 | 19 | 26 | 17 | 23 | 21 |
| Max | 452 | 458 | 451 | 454 | 441 | 466 | 505 | 450 | 455 | 481 | 450 | 479 | 448 |
| Min | 374 | 368 | 360 | 385 | 390 | 380 | 391 | 388 | 382 | 395 | 390 | 394 | 370 |

Units: msec

Table 12d-5
ECG-QTc Interval

| Subj | Day 39 Pre | Day 42 Pre | Day 42 .5hr | Day 42 1hr | Day 42 2hr | Day 42 3hr | Day 42 4hr | Day 42 6hr | Day 42 8hr | Day 42 10hr | Day 42 12hr | Day 43 AM | Day 44 AM |
|---------|---------------|---------------|----------------|---------------|---------------|---------------|---------------|---------------|---------------|----------------|----------------|--------------|--------------|
| 01 | 403 | 407 | 405 | 406 | 405 | 456 | 397 | 369 | 425 | 398 | 406 | 407 | 412 |
| 02 | 427 | | | | | | | | | | | | |
| 03 | 385 | 401 | 387 | 385 | 403 | 377 | 353 | 376 | 385 | 376 | 395 | 401 | 401 |
| 04 | | | | | | | | | | | | | |
| 05 | | | | | | | | | | | | | |
| 06 | 385 | 371 | 376 | 364 | 361 | 345 | 394 | 354 | 362 | 343 | 352 | 382 | 352 |
| 07 | 453 | 424 | 427 | 428 | 423 | 420 | 416 | 419 | 421 | 430 | 417 | 364 | 442 |
| 08 | | | | | | | | | | | | | |
| 09 | 419 | 415 | 470 | 387 | 391 | 417 | 413 | 413 | 419 | 424 | 420 | 418 | 413 |
| 10 | 414 | 413 | 373 | 392 | 379 | 445 | 436 | 411 | 410 | 419 | 418 | 430 | 415 |
| 11 | 452 | 473 | 434 | 418 | 451 | 491 | 476 | 478 | 471 | 425 | 450 | 434 | 427 |
| 12 | 408 | 404 | 408 | 378 | 398 | 402 | 405 | 353 | 369 | 399 | 404 | 391 | 411 |
| 13 | 409 | 383 | 408 | 415 | 411 | 374 | 390 | 375 | 375 | 383 | 395 | 396 | 422 |
| 14 | 438 | | | | | | | | | | | | |
| 15 | 404 | 406 | 393 | 410 | 392 | 414 | 389 | 408 | 404 | 402 | 420 | 415 | 401 |
| 16 | 427 | 438 | 420 | 407 | 403 | 433 | 408 | 416 | 414 | 410 | 415 | 419 | 422 |
| 17 | | | | | | | | | | | | | |
| 18 | | 475 | 462 | 456 | 434 | 464 | 454 | 420 | 415 | 426 | 428 | 423 | 445 |
| 19 | 401 | 440 | 409 | 398 | 405 | 416 | 406 | 403 | 410 | 403 | 410 | 406 | 398 |
| 20 | 421 | 438 | 437 | 425 | 428 | 442 | 442 | 435 | 420 | 416 | 425 | 414 | 411 |
| 21 | 416 | 415 | 407 | 411 | 413 | 420 | 407 | 405 | 403 | 408 | 411 | 401 | 411 |
| Summary | | | | | | | | | | | | | |
| Average | 416 | 420 | 414 | 405 | 406 | 421 | 412 | 402 | 407 | 404 | 411 | 407 | 412 |
| Std Dev | 20 | 29 | 28 | 23 | 22 | 37 | 30 | 33 | 27 | 23 | 21 | 19 | 21 |
| Max | 453 | 475 | 470 | 456 | 451 | 491 | 476 | 478 | 471 | 430 | 450 | 434 | 445 |
| Min | 385 | 371 | 373 | 364 | 361 | 345 | 353 | 353 | 362 | 343 | 352 | 364 | 352 |

Blank = Not Obtained

Units: msec

Table 12d-6
ECG-QTc Interval

Blank = Not Obtained

| Subj | Day 45 AM | Day 48 AM | Day 51 AM | Day 54 AM | Day 57 AM | Day 72 AM | Day 180 AM |
|---------|--------------|--------------|--------------|--------------|--------------|--------------|---------------|
| 01 | 396 | 385 | 383 | 396 | 398 | 410 | 397 |
| 02 | | | | | | | |
| 03 | 404 | 403 | 404 | 385 | 397 | 401 | 406 |
| 04 | | | | | | | |
| 05 | | | | | | | |
| 06 | 337 | 384 | 389 | 388 | 385 | 375 | 402 |
| 07 | 432 | 428 | 444 | 428 | 424 | | 424 |
| 08 | | | | | | | |
| 09 | | 404 | 454 | 384 | 433 | 367 | 388 |
| 10 | | 406 | 411 | 404 | | | |
| 11 | 463 | | | | | | |
| 12 | 394 | 403 | 406 | 398 | 415 | 360 | 411 |
| 13 | 421 | 408 | 404 | 404 | 406 | 412 | 394 |
| 14 | | | | | | | |
| 15 | 395 | 389 | 399 | 347 | 383 | 432 | 397 |
| 16 | | | | | | 399 | 416 |
| 17 | | | | | | | |
| 18 | 440 | | 424 | 419 | 415 | 416 | |
| 19 | 393 | 406 | 415 | 367 | 401 | 403 | |
| 20 | 411 | 412 | 414 | 407 | 382 | 409 | |
| 21 | 422 | 434 | 410 | 468 | 411 | 446 | |
| Summary | | | | | | | |
| Average | 409 | 405 | 412 | 400 | 404 | 403 | 404 |
| Std Dev | 31 | 15 | 20 | 29 | 16 | 25 | 11 |
| Max | 463 | 434 | 454 | 468 | 433 | 446 | 424 |
| Min | 337 | 384 | 383 | 347 | 382 | 360 | 388 |

Figure 54: SD & Range Charts for ECG - QTc Interval, msec

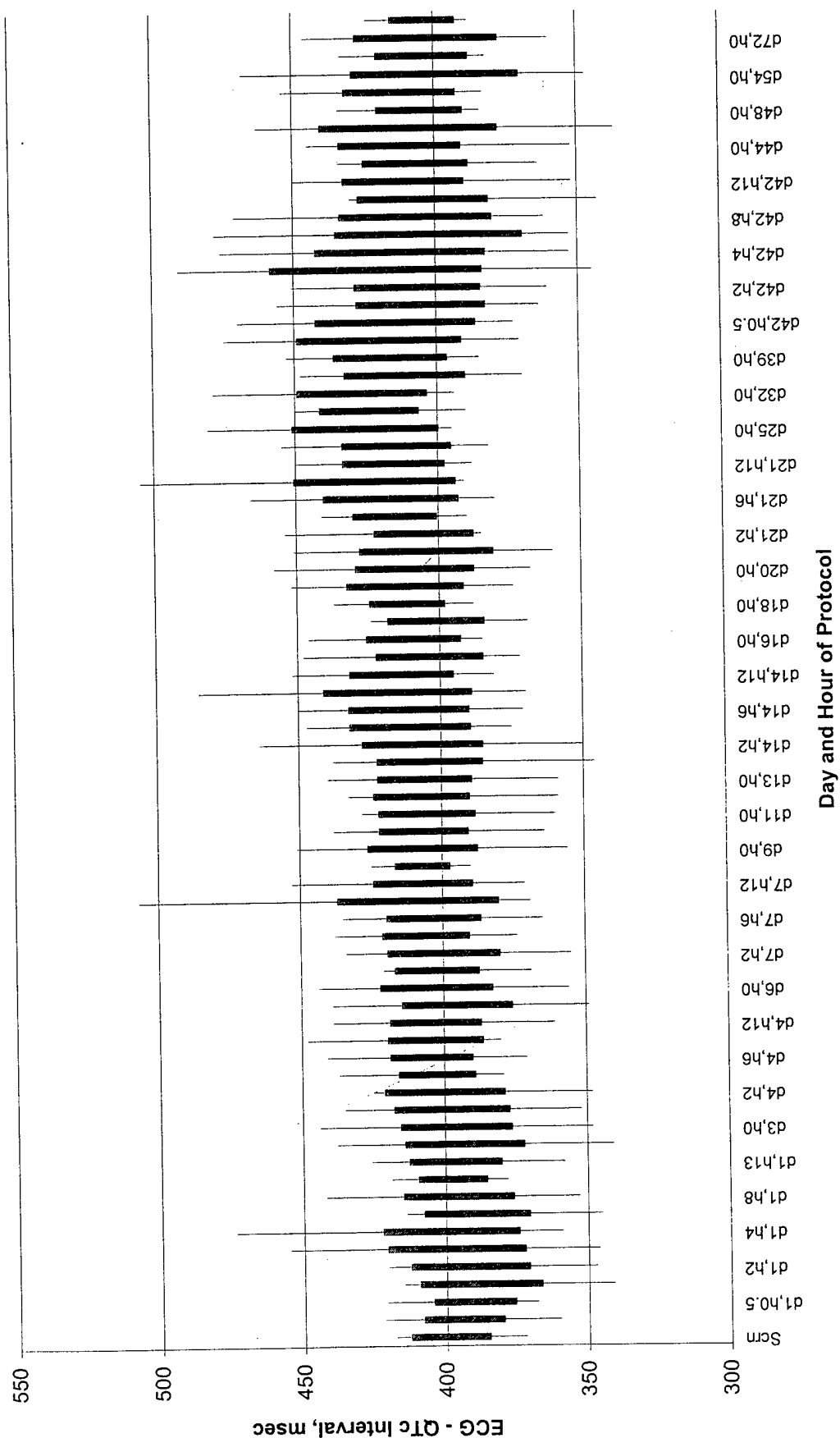


Table 13a-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 01

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 399 | | | | |
| 1 | .5HR | 397 | | | | |
| 1 | 1HR | 403 | | | | |
| 1 | 2HR | 384 | | | | |
| 1 | 3HR | 371 | | | | 16.4 |
| 1 | 4HR | 407 | 10.9 | | | 20.9 |
| 1 | 6HR | 396 | 15.1 | | | 18.5 |
| 1 | 8HR | 393 | 15 | | | 27 |
| 1 | 10HR | 402 | 17.2 | 10.4 | | 27.7 |
| 1 | 12HR | 391 | 12.9 | | | 22.3 |
| 2 | PRE | 381 | | | | 23.2 |
| 3 | PRE | 392 | 10.9 | | | 29.5 |
| 4 | PRE | 389 | 32 | | | 36.4 |
| 4 | 2HR | 386 | 30.6 | 22.8 | | 38.4 |
| 4 | 4HR | 398 | 73.2 | 41.7 | | 44.3 |
| 4 | 6HR | 409 | 47.9 | 37.7 | | 84.7 |
| 4 | 8HR | 382 | 38.9 | 17.1 | | 52.4 |
| 4 | 12HR | 399 | 54.6 | 30.7 | | 64.7 |
| 5 | PRE | 375 | 25.9 | 22.5 | 17.2 | 76.2 |
| 6 | PRE | 393 | 37.9 | 16.5 | 20.8 | 108 |
| 7 | PRE | 369 | 43.4 | 18.2 | 26.1 | 128 |
| 7 | 2HR | 411 | 55.8 | 33.7 | 16.8 | 74.1 |
| 7 | 4HR | 402 | 93.4 | 59.3 | 32.6 | 153 |
| 7 | 6HR | 399 | 131 | 73.1 | 37.2 | 202 |
| 7 | 8HR | 389 | 144 | 79.6 | 74 | 203 |
| 7 | 12HR | 403 | 101 | 50.6 | 56.4 | 149 |
| 8 | PRE | 405 | 57.6 | 27.4 | 62.7 | 183 |
| 9 | PRE | 398 | 77.2 | 33.1 | 72.6 | 221 |
| 10 | PRE | 403 | 68.9 | 28 | 87.8 | 282 |
| 11 | PRE | 389 | 50.6 | 20.4 | 54.2 | 227 |
| 12 | PRE | 389 | 51.3 | 20.8 | 45.3 | 325 |
| 13 | PRE | 404 | 55.9 | 25.4 | 44.1 | 334 |
| 14 | PRE | 396 | 58.6 | 25.5 | 29.7 | 311 |
| 14 | 2HR | 404 | 65.6 | 30.3 | 22.8 | 211 |
| 14 | 4HR | 404 | | | | |
| 14 | 6HR | 402 | 73.3 | 37.4 | 36.4 | 324 |
| 14 | 8HR | 406 | 68.2 | 36.2 | 32.2 | 318 |
| 14 | 12HR | 404 | 80.8 | 35 | 35 | 260 |

Table 13a-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 01

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 427 | 68.3 | 32.8 | 41.1 | 409 |
| 16 | PRE | 404 | 80.6 | 36.6 | 32.6 | 361 |
| 17 | PRE | 400 | 84.5 | 37.4 | 38.8 | 497 |
| 18 | PRE | 396 | 92.8 | 41 | 59.1 | 532 |
| 19 | PRE | 409 | 94.6 | 51.7 | 51 | 435 |
| 20 | PRE | 400 | 127 | 70 | 59.1 | 496 |
| 21 | PRE | 421 | 81 | 40.6 | 32.2 | 290 |
| 21 | 2HR | 402 | 96.8 | 51.7 | 30.5 | 251 |
| 21 | 4HR | 423 | 52.5 | 24.4 | 38.2 | 295 |
| 21 | 6HR | 416 | 70.5 | 31.1 | 54.4 | 386 |
| 21 | 8HR | 450 | 169 | 93.7 | 51.2 | 335 |
| 21 | 12HR | 449 | 82.4 | 35.8 | 33.6 | 385 |
| 22 | PRE | | 59.2 | 25.9 | 49 | 329 |
| 25 | PRE | 407 | 54.6 | 26.7 | 29.3 | 289 |
| 29 | PRE | 403 | 54.4 | 23.7 | 30.9 | 355 |
| 32 | PRE | 407 | 109 | 50.2 | 52.8 | 484 |
| 33 | PRE | 405 | 121 | 55.8 | 63.5 | 506 |
| 36 | PRE | 406 | 112 | 56 | 53 | 468 |
| 39 | PRE | 405 | 134 | 68 | 67 | 535 |
| 42 | PRE | 456 | 160 | 88.2 | 66.8 | 687 |
| 42 | .5HR | 397 | 157 | 91.4 | 53.8 | 565 |
| 42 | 1HR | 369 | 181 | 106 | 59.1 | 576 |
| 42 | 2HR | 425 | 193 | 110 | 61.1 | 538 |
| 42 | 3HR | 398 | 153 | 93.7 | 32.6 | 339 |
| 42 | 4HR | 406 | 168 | 90.5 | 77.7 | 633 |
| 42 | 6HR | 407 | 64 | 35.2 | 29.7 | 224 |
| 42 | 8HR | 412 | 67.9 | 27.6 | 39 | 424 |
| 42 | 10HR | 396 | 46.3 | 18.8 | 37.8 | 508 |
| 42 | 12HR | 385 | 46.7 | 18.4 | 15.8 | 340 |
| 43 | AM | 383 | 34.9 | 12.7 | | 255 |
| 44 | AM | 396 | 29.9 | 10.4 | | 175 |
| 45 | AM | 398 | 32.1 | 12.3 | | 128 |
| 48 | AM | 410 | 33.8 | 15.2 | 27.7 | 243 |
| 51 | AM | 397 | | | | 16.4 |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13b-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 02

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 404 | | | | |
| 1 | .5HR | 409 | | | | |
| 1 | 1HR | 405 | | | | |
| 1 | 2HR | 387 | | | | |
| 1 | 3HR | 419 | | | | |
| 1 | 4HR | 410 | | | | |
| 1 | 6HR | 382 | 31.5 | 22.7 | | |
| 1 | 8HR | 442 | 25 | 35.1 | | |
| 1 | 10HR | 411 | 29.5 | 20.1 | | |
| 1 | 12HR | 414 | 20.1 | 12.3 | | |
| 2 | PRE | 399 | 13 | | | |
| 3 | PRE | 408 | | | | |
| 4 | PRE | 393 | 30.4 | 16.5 | | 31.5 |
| 4 | 2HR | 413 | 37.7 | 37.1 | | 60.6 |
| 4 | 4HR | 408 | 79.1 | 55.5 | 19 | 61.2 |
| 4 | 6HR | 417 | 63.5 | 38.7 | | 63.6 |
| 4 | 8HR | 413 | 46.4 | 26.3 | | 34.7 |
| 4 | 12HR | 413 | 33.1 | 18.1 | | 53 |
| 5 | PRE | 406 | 26.9 | 16.6 | | 55.8 |
| 6 | PRE | 412 | 29.7 | 16.6 | | 77.7 |
| 7 | PRE | 409 | 30.3 | 14.8 | 18 | 84.4 |
| 7 | 2HR | 401 | 31.2 | 19.2 | 16.8 | 71.8 |
| 7 | 4HR | 408 | 78.4 | 53.7 | 29.7 | 121 |
| 7 | 6HR | 419 | 72.8 | 43 | 17.6 | 78.1 |
| 7 | 8HR | 507 | 67.9 | 41.4 | 23.3 | 91.8 |
| 7 | 12HR | 420 | 48.6 | 25.9 | 29.3 | 100 |
| 8 | PRE | 425 | 30.3 | 15.7 | 20.2 | 93.8 |
| 9 | PRE | 419 | 50.7 | 27 | 23.9 | 101 |
| 10 | PRE | 406 | 61 | 27.8 | 31.1 | 140 |
| 11 | PRE | 428 | 64.4 | 32.7 | 34.3 | 174 |
| 12 | PRE | 433 | 69.7 | 33.2 | 36.6 | 174 |
| 13 | PRE | 418 | 79.8 | 43.4 | 36 | 194 |
| 14 | PRE | 413 | 52.8 | 25 | 32.9 | 161 |
| 14 | 2HR | 464 | 75.5 | 46.7 | 29.7 | 160 |
| 14 | 4HR | 416 | 83.9 | 51.8 | 36 | 188 |
| 14 | 6HR | 450 | 107 | 62.5 | 39.8 | 229 |
| 14 | 8HR | 422 | 123 | 71.9 | 42.8 | 232 |
| 14 | 12HR | 452 | 84.2 | 46 | 36 | 201 |

Table 13b-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 02

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 434 | 104 | 59.8 | 39.4 | 218 |
| 16 | PRE | 432 | 125 | 66.4 | 39.6 | 219 |
| 17 | PRE | 428 | 83.1 | 40.8 | 33.9 | 193 |
| 18 | PRE | 393 | 139 | 99.5 | 36.6 | 209 |
| 19 | PRE | 419 | 273 | 240 | 43.4 | 263 |
| 20 | PRE | 466 | 369 | 298 | 52.3 | 274 |
| 21 | PRE | 505 | 319 | 239 | 59.7 | 336 |
| 21 | 2HR | 450 | 263 | 179 | 62 | 372 |
| 21 | 4HR | 455 | 127 | 75.4 | 35.6 | 243 |
| 21 | 6HR | 462 | 108 | 60.4 | 53.3 | 289 |
| 21 | 8HR | 432 | 195 | 122 | 48.9 | 292 |
| 21 | 12HR | 479 | 111 | 60.6 | 74.9 | 432 |
| 22 | PRE | | 65.9 | 31.2 | 57.9 | 431 |
| 25 | PRE | 441 | 60.8 | 33.2 | 60.8 | 459 |
| 29 | PRE | 427 | | | | |
| 32 | PRE | | | | | |
| 33 | PRE | | | | | |
| 36 | PRE | | | | | |
| 39 | PRE | | | | | |
| 42 | PRE | | | | | |
| 42 | .5HR | | | | | |
| 42 | 1HR | | | | | |
| 42 | 2HR | | | | | |
| 42 | 3HR | | | | | |
| 42 | 4HR | | | | | |
| 42 | 6HR | | | | | |
| 42 | 8HR | | | | | |
| 42 | 10HR | | | | | |
| 42 | 12HR | | | | | |
| 43 | AM | | | | | |
| 44 | AM | | | | | |
| 45 | AM | | | | | |
| 48 | AM | | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13c-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 04

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 383 | | | | |
| 1 | .5HR | 389 | | | | |
| 1 | 1HR | 373 | | | | |
| 1 | 2HR | 376 | 16.4 | 12.6 | | |
| 1 | 3HR | 398 | 52.6 | 37.9 | | 18.6 |
| 1 | 4HR | 395 | 35.1 | 20.5 | | 20.1 |
| 1 | 6HR | 395 | 71.1 | 32.8 | 20.9 | 46 |
| 1 | 8HR | 396 | 44.5 | 19 | 18.5 | 47.1 |
| 1 | 10HR | 389 | 18.9 | | | 33.9 |
| 1 | 12HR | 397 | 29.6 | 10.2 | | 40.7 |
| 2 | PRE | 388 | 14.6 | | 18 | 38 |
| 3 | PRE | 401 | 25.6 | 10.7 | 20.1 | 69.5 |
| 4 | PRE | 411 | 79.9 | 41.8 | 30.3 | 96.8 |
| 4 | 2HR | 423 | 308 | 356 | 62 | 199 |
| 4 | 4HR | 398 | 348 | 329 | 40.5 | 125 |
| 4 | 6HR | 398 | 446 | 310 | 54.8 | 165 |
| 4 | 8HR | 417 | 292 | 191 | 55.3 | 192 |
| 4 | 12HR | 404 | 246 | 146 | 51.5 | 181 |
| 5 | PRE | 399 | 107 | 57.9 | 65.8 | 211 |
| 6 | PRE | 411 | 132 | 74.4 | 53.7 | 234 |
| 7 | PRE | 406 | 85.6 | 38.6 | 52.1 | 260 |
| 7 | 2HR | 398 | 109 | 60.3 | 45.9 | 242 |
| 7 | 4HR | 402 | 183 | 107 | 64.7 | 314 |
| 7 | 6HR | 396 | 141 | 72.5 | 44.6 | 207 |
| 7 | 8HR | 400 | 111 | 55.7 | 32.2 | 149 |
| 7 | 12HR | 402 | 109 | 49.7 | 28.2 | 134 |
| 8 | PRE | 398 | 97.9 | 35 | 20.1 | 92.4 |
| 9 | PRE | 400 | 69.2 | 30 | 24.4 | 138 |
| 10 | PRE | 398 | 70.6 | 29.8 | 26.3 | 138 |
| 11 | PRE | 401 | 68.9 | 30.3 | 30.3 | 175 |
| 12 | PRE | 400 | 73.1 | 32.2 | 21.5 | 135 |
| 13 | PRE | 400 | 74.5 | 28.1 | 23.9 | 121 |
| 14 | PRE | 401 | 124 | 52.7 | 31.4 | 200 |
| 14 | 2HR | 402 | 110 | 50.2 | 32.5 | 160 |
| 14 | 4HR | 398 | 205 | 104 | 33 | 174 |
| 14 | 6HR | 404 | 234 | 119 | 39.5 | 193 |
| 14 | 8HR | 399 | 166 | 79.4 | 27.9 | 124 |
| 14 | 12HR | 402 | 117 | 51.6 | 22.5 | 114 |

Table 13c-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 04

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 399 | 66.4 | 28.1 | 40.8 | 264 |
| 16 | PRE | 402 | 81.4 | 31.5 | 46.7 | 313 |
| 17 | PRE | 402 | 97.7 | 38.6 | 45.4 | 283 |
| 18 | PRE | 402 | 137 | 62.7 | 67.4 | 449 |
| 19 | PRE | 409 | 195 | 113 | 41.1 | 303 |
| 20 | PRE | 406 | 224 | 122 | 45.1 | 285 |
| 21 | PRE | 411 | 190 | 95.4 | 67.1 | 368 |
| 21 | 2HR | 408 | 146 | 63.9 | 57.2 | 330 |
| 21 | 4HR | 427 | 92.8 | 36.9 | 43.8 | 296 |
| 21 | 6HR | 420 | 84 | 32.8 | 59.3 | 349 |
| 21 | 8HR | 414 | 75.9 | 28.5 | 60.4 | 318 |
| 21 | 12HR | 404 | 105 | 40.2 | 54 | 411 |
| 22 | PRE | | | | | |
| 25 | PRE | 402 | 59.1 | 23.5 | 45.4 | 259 |
| 29 | PRE | | 52.2 | 19.2 | 31.4 | 219 |
| 32 | PRE | | | | | |
| 33 | PRE | | | | | |
| 36 | PRE | | | | | |
| 39 | PRE | | | | | |
| 42 | PRE | | | | | |
| 42 | .5HR | | | | | |
| 42 | 1HR | | | | | |
| 42 | 2HR | | | | | |
| 42 | 3HR | | | | | |
| 42 | 4HR | | | | | |
| 42 | 6HR | | | | | |
| 42 | 8HR | | | | | |
| 42 | 10HR | | | | | |
| 42 | 12HR | | | | | |
| 43 | AM | | | | | |
| 44 | AM | | | | | |
| 45 | AM | | | | | |
| 48 | AM | | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13d-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 05

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 390 | | | | |
| 1 | .5HR | 376 | | | | |
| 1 | 1HR | 394 | 11.4 | 10.7 | | |
| 1 | 2HR | 407 | 19.9 | 17.2 | | |
| 1 | 3HR | 372 | 19.5 | 15.1 | | 15 |
| 1 | 4HR | 373 | 15.1 | | | 15 |
| 1 | 6HR | 387 | 34.7 | 18.6 | | 29.3 |
| 1 | 8HR | 383 | 20.3 | 10.3 | | 18.7 |
| 1 | 10HR | 404 | 37.4 | 16.3 | | 47.3 |
| 1 | 12HR | 404 | 14.5 | | | 18.4 |
| 2 | PRE | 388 | | | | 29.3 |
| 3 | PRE | 383 | 14.3 | | | 54.2 |
| 4 | PRE | 403 | 20.1 | 13.1 | | 46.4 |
| 4 | 2HR | 397 | 22.2 | 15.1 | | 40.5 |
| 4 | 4HR | 381 | 78.6 | 44.2 | | 88 |
| 4 | 6HR | 410 | 50.2 | 27 | | 70 |
| 4 | 8HR | 402 | 67.3 | 32.6 | 22.4 | 98.6 |
| 4 | 12HR | 391 | 52.6 | 25.5 | 20.7 | 97 |
| 5 | PRE | 382 | 26.7 | 11.7 | 28.8 | 118 |
| 6 | PRE | 415 | 26.1 | | 16.2 | 100 |
| 7 | PRE | 411 | 27.2 | 11.2 | 17.9 | 136 |
| 7 | 2HR | 374 | 19.4 | 11.4 | 15.6 | 79.3 |
| 7 | 4HR | 395 | 43.3 | 23.9 | 26 | 175 |
| 7 | 6HR | 399 | 58.7 | 31.8 | 26 | 199 |
| 7 | 8HR | 369 | 37.8 | 18.6 | 18.7 | 139 |
| 7 | 12HR | 413 | 31.9 | 14.8 | | 83 |
| 8 | PRE | 400 | 28.4 | 12.3 | 17.9 | 131 |
| 9 | PRE | 389 | 33 | 15.4 | 27.4 | 179 |
| 10 | PRE | 396 | 35.8 | 14 | 23.2 | 155 |
| 11 | PRE | 405 | 27.8 | 11.4 | 22.1 | 161 |
| 12 | PRE | 403 | 34.8 | 14.9 | 19.8 | 186 |
| 13 | PRE | 416 | 35.3 | 16 | 26.6 | 283 |
| 14 | PRE | 417 | 51.6 | 26.9 | 32.2 | 304 |
| 14 | 2HR | 395 | 56.4 | 35.1 | 19.8 | 192 |
| 14 | 4HR | 396 | 116 | 66.5 | 55.4 | 453 |
| 14 | 6HR | 409 | 74 | 41.3 | 36.1 | 274 |
| 14 | 8HR | 370 | 67.4 | 35.2 | 29.4 | 235 |
| 14 | 12HR | 401 | 46.4 | 23 | 29.1 | 198 |

Table 13d-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 05

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 407 | 50 | 23.1 | 29.1 | 297 |
| 16 | PRE | 400 | 39.4 | 18.2 | 30.5 | 331 |
| 17 | PRE | 390 | 40.5 | 19 | 39.7 | 340 |
| 18 | PRE | 385 | 75.1 | 46.2 | 31.9 | 333 |
| 19 | PRE | 403 | 79.3 | 41.9 | 32.2 | 312 |
| 20 | PRE | 380 | 95.3 | 55.1 | 48.4 | 438 |
| 21 | PRE | 415 | 62.2 | 32.9 | 31.9 | 260 |
| 21 | 2HR | 389 | 54.3 | 28.7 | 47.3 | 401 |
| 21 | 4HR | 395 | 35.9 | 16.8 | 24.9 | 246 |
| 21 | 6HR | 395 | 31.3 | 14.8 | 29.4 | 32.1 |
| 21 | 8HR | | | | | |
| 21 | 12HR | | | | | |
| 22 | PRE | | | | | |
| 25 | PRE | | | | | |
| 29 | PRE | | | | | |
| 32 | PRE | | | | | |
| 33 | PRE | | | | | |
| 36 | PRE | | | | | |
| 39 | PRE | | | | | |
| 42 | PRE | | | | | |
| 42 | .5HR | | | | | |
| 42 | 1HR | | | | | |
| 42 | 2HR | | | | | |
| 42 | 3HR | | | | | |
| 42 | 4HR | | | | | |
| 42 | 6HR | | | | | |
| 42 | 8HR | | | | | |
| 42 | 10HR | | | | | |
| 42 | 12HR | | | | | |
| 43 | AM | | | | | |
| 44 | AM | | 14.2 | | | 20.9 |
| 45 | AM | | | | | |
| 48 | AM | | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13e-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 07

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 398 | | | | |
| 1 | .5HR | 378 | | | | |
| 1 | 1HR | 403 | | | | |
| 1 | 2HR | 420 | 10.8 | | | |
| 1 | 3HR | 409 | 14.9 | 10.6 | | |
| 1 | 4HR | 408 | 28.4 | 18.7 | | 15.8 |
| 1 | 6HR | 364 | 23.3 | 15.6 | | 15.8 |
| 1 | 8HR | 368 | 23.5 | 15.6 | | 17.6 |
| 1 | 10HR | 396 | 20.9 | 14.1 | | 18.3 |
| 1 | 12HR | 406 | 17.5 | 12.5 | | |
| 2 | PRE | 388 | 10.3 | 10.6 | | |
| 3 | PRE | 391 | 50.8 | 36.6 | | 38.9 |
| 4 | PRE | 410 | 75.4 | 48.3 | 22.6 | 71.8 |
| 4 | 2HR | 388 | 342 | 326 | 34.6 | 92.8 |
| 4 | 4HR | 423 | 572 | 570 | | 110 |
| 4 | 6HR | 414 | 456 | 343 | 50.3 | 135 |
| 4 | 8HR | 413 | 290 | 223 | 40.2 | 131 |
| 4 | 12HR | 417 | 235 | 158 | 39.3 | 101 |
| 5 | PRE | 403 | 88.4 | 56.5 | 22.9 | 93.8 |
| 6 | PRE | 410 | 73.3 | 45 | 31.7 | 132 |
| 7 | PRE | 414 | 149 | 85.6 | 80.9 | 211 |
| 7 | 2HR | 398 | 186 | 128 | 40.9 | 202 |
| 7 | 4HR | 435 | 184 | 127 | 28.6 | 106 |
| 7 | 6HR | 419 | 227 | 152 | 40.6 | 150 |
| 7 | 8HR | 411 | 229 | 152 | 42.8 | 135 |
| 7 | 12HR | 453 | 180 | 117 | 42.4 | 138 |
| 8 | PRE | 418 | 108 | 67.3 | 24.8 | 113 |
| 9 | PRE | 418 | 89.1 | 56 | 21.3 | 102 |
| 10 | PRE | 414 | 105 | 58.8 | 27 | 132 |
| 11 | PRE | 401 | 121 | 71.5 | 33.9 | 138 |
| 12 | PRE | 423 | 112 | 63.8 | 25.7 | 123 |
| 13 | PRE | 412 | 145 | 74.5 | 27.9 | 128 |
| 14 | PRE | 408 | 142 | 75.9 | 27.9 | 174 |
| 14 | 2HR | 407 | 142 | 84.8 | 27 | 163 |
| 14 | 4HR | 446 | 265 | 161 | 32 | 138 |
| 14 | 6HR | 440 | 264 | 154 | 41.5 | 180 |
| 14 | 8HR | 485 | 213 | 115 | 33 | 143 |
| 14 | 12HR | 424 | 232 | 124 | 43.7 | 187 |

Table 13e-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 07

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 420 | 150 | 72.4 | 32.7 | 166 |
| 16 | PRE | 412 | 160 | 79 | 36.1 | 174 |
| 17 | PRE | 440 | 226 | 110 | 54.8 | 257 |
| 18 | PRE | 432 | 272 | 156 | 52.5 | 246 |
| 19 | PRE | 423 | 292 | 152 | 61.7 | 279 |
| 20 | PRE | 420 | 312 | 171 | 62 | 260 |
| 21 | PRE | 432 | 258 | 130 | 48.4 | 211 |
| 21 | 2HR | 431 | 250 | 121 | 50.3 | 212 |
| 21 | 4HR | 424 | 170 | 80.8 | 41.8 | 205 |
| 21 | 6HR | 481 | 162 | 73.2 | 42.4 | 184 |
| 21 | 8HR | 440 | 123 | 57 | 38.7 | 177 |
| 21 | 12HR | 456 | 155 | 78 | 51.6 | 297 |
| 22 | PRE | | 93.9 | 55.7 | 34.9 | 189 |
| 25 | PRE | 405 | 116 | 60.2 | 47.5 | 267 |
| 29 | PRE | 453 | 206 | 97.6 | 61.1 | 312 |
| 32 | PRE | 424 | 182 | 80.6 | 79.7 | 402 |
| 33 | PRE | 427 | 123 | 56.2 | 61.1 | 246 |
| 36 | PRE | 428 | 150 | 71.5 | 63.3 | 289 |
| 39 | PRE | 423 | 151 | 79.1 | 55.4 | 244 |
| 42 | PRE | 420 | 165 | 81.7 | 47.8 | 277 |
| 42 | .5HR | 416 | 204 | 106 | 59.8 | 382 |
| 42 | 1HR | 419 | 172 | 83.2 | 47.2 | 350 |
| 42 | 2HR | 421 | 202 | 95.6 | 63.3 | 408 |
| 42 | 3HR | 430 | 224 | 92.9 | 56.3 | 335 |
| 42 | 4HR | 417 | 201 | 88.5 | 53.8 | 353 |
| 42 | 6HR | 364 | 175 | 72.7 | 60.1 | 382 |
| 42 | 8HR | 442 | | | | |
| 42 | 10HR | 432 | 68.6 | 45.2 | 20.7 | 217 |
| 42 | 12HR | 428 | | | | |
| 43 | AM | 444 | 42 | 18.7 | | 97.3 |
| 44 | AM | 428 | 46.6 | 21.1 | | 48 |
| 45 | AM | 424 | 49.9 | 21.6 | | 51.5 |
| 48 | AM | | 29.2 | 23.4 | | 17.2 |
| 51 | AM | 424 | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13f-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 08

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 372 | | | | |
| 1 | .5HR | 371 | | | | |
| 1 | 1HR | 380 | 15.9 | 13.9 | | |
| 1 | 2HR | 380 | 37.6 | 32.9 | | |
| 1 | 3HR | 366 | 65.3 | 50.3 | | 33.1 |
| 1 | 4HR | 371 | 78.9 | 57.7 | 16.4 | 35.7 |
| 1 | 6HR | 401 | 162 | 113 | 18.8 | 50.5 |
| 1 | 8HR | 383 | 102 | 69.7 | 21.5 | 51.5 |
| 1 | 10HR | 379 | 61.9 | 41.7 | | 37.1 |
| 1 | 12HR | 383 | 62.1 | 40.3 | | 41.4 |
| 2 | PRE | 383 | 24.1 | 13.6 | | 33.4 |
| 3 | PRE | 384 | 45.5 | 21.7 | | 44.1 |
| 4 | PRE | 377 | 33.2 | 19.9 | 17.3 | 76.5 |
| 4 | 2HR | 372 | 67.3 | 49.8 | 26 | 100 |
| 4 | 4HR | 388 | 152 | 113 | 47.2 | 199 |
| 4 | 6HR | 404 | 114 | 75.4 | 27.2 | 110 |
| 4 | 8HR | 382 | 103 | 66.6 | 33.9 | 129 |
| 4 | 12HR | 407 | 136 | 76.7 | 37.8 | 132 |
| 5 | PRE | 385 | 40.9 | 22.4 | 26.9 | 115 |
| 6 | PRE | 385 | 51.8 | 25.1 | 31.8 | 139 |
| 7 | PRE | 387 | 74.3 | 41.7 | 46 | 245 |
| 7 | 2HR | 398 | 94.6 | 63 | 46.3 | 205 |
| 7 | 4HR | 409 | 132 | 85.4 | 61.4 | 310 |
| 7 | 6HR | 394 | 142 | 83.8 | 74.1 | 351 |
| 7 | 8HR | 398 | 136 | 79.3 | 59.9 | 296 |
| 7 | 12HR | 384 | 111 | 62.1 | 54.2 | 286 |
| 8 | PRE | 402 | 63.1 | 31.7 | 38.4 | 211 |
| 9 | PRE | 417 | 101 | 53.4 | 59 | 283 |
| 10 | PRE | 390 | 76.4 | 40.8 | 65 | 363 |
| 11 | PRE | | | | | |
| 12 | PRE | | | | | |
| 13 | PRE | | | | | |
| 14 | PRE | | | | | |
| 14 | 2HR | | | | | |
| 14 | 4HR | | | | | |
| 14 | 6HR | | | | | |
| 14 | 8HR | | | | | |
| 14 | 12HR | | | | | |

Table 13f-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 08

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | | | | | |
| 16 | PRE | | | | | |
| 17 | PRE | | | | | |
| 18 | PRE | | | | | |
| 19 | PRE | | | | | |
| 20 | PRE | | | | | |
| 21 | PRE | | | | | |
| 21 | 2HR | | | | | |
| 21 | 4HR | | | | | |
| 21 | 6HR | | | | | |
| 21 | 8HR | | | | | |
| 21 | 12HR | | | | | |
| 22 | PRE | | | | | |
| 25 | PRE | | | | | |
| 29 | PRE | | | | | |
| 32 | PRE | | | | | |
| 33 | PRE | | | | | |
| 36 | PRE | | | | | |
| 39 | PRE | | | | | |
| 42 | PRE | | | | | |
| 42 | .5HR | | | | | |
| 42 | 1HR | | | | | |
| 42 | 2HR | | | | | |
| 42 | 3HR | | | | | |
| 42 | 4HR | | | | | |
| 42 | 6HR | | | | | |
| 42 | 8HR | | | | | |
| 42 | 10HR | | | | | |
| 42 | 12HR | | | | | |
| 43 | AM | | | | | |
| 44 | AM | | | | | |
| 45 | AM | | | | | |
| 48 | AM | | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13g-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 09

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 395 | | | | |
| 1 | .5HR | 374 | | | | |
| 1 | 1HR | 375 | | | | |
| 1 | 2HR | 359 | 12.6 | 11.2 | | |
| 1 | 3HR | | 70.9 | 61.8 | | |
| 1 | 4HR | 386 | 152 | 132 | | 20.4 |
| 1 | 6HR | 401 | 122 | 102 | | 24.3 |
| 1 | 8HR | 391 | 103 | 81.4 | | 27.6 |
| 1 | 10HR | 381 | 65 | 47 | | 26.6 |
| 1 | 12HR | 391 | 53.8 | 37.4 | | 23 |
| 2 | PRE | 368 | 21 | 15.2 | | 24 |
| 3 | PRE | 393 | 20.6 | 13.4 | | 33.2 |
| 4 | PRE | 416 | 24.2 | 16.5 | | 44.1 |
| 4 | 2HR | 384 | 42.8 | 29.5 | | 51.7 |
| 4 | 4HR | 403 | 109 | 73.3 | 23.1 | 78.5 |
| 4 | 6HR | 391 | 95.8 | 63.6 | 15.2 | 64.3 |
| 4 | 8HR | 385 | 60.5 | 42.5 | 16.6 | 55 |
| 4 | 12HR | 409 | 38.6 | 24.1 | 15.7 | 44.1 |
| 5 | PRE | 384 | 27 | 17.5 | 17.8 | 85.8 |
| 6 | PRE | 397 | 36.7 | 20.5 | 15.2 | 62.6 |
| 7 | PRE | 372 | 40.9 | 23.4 | 21.7 | 111 |
| 7 | 2HR | 358 | 36.1 | 21.4 | 18.7 | 79.8 |
| 7 | 4HR | 389 | 122 | 86.7 | 41.5 | 194 |
| 7 | 6HR | 407 | 122 | 87 | 33.2 | 176 |
| 7 | 8HR | 396 | 94.1 | 60.8 | 28.5 | 125 |
| 7 | 12HR | 406 | 64.8 | 43.5 | 35.3 | 164 |
| 8 | PRE | 399 | 44.6 | 28 | 29.1 | 158 |
| 9 | PRE | 428 | 57.4 | 35.1 | 29.7 | 138 |
| 10 | PRE | 411 | 51.6 | 29 | 25.5 | 153 |
| 11 | PRE | 391 | 60.3 | 36.9 | 45.3 | 240 |
| 12 | PRE | 413 | 65.4 | 43.4 | 36.8 | 228 |
| 13 | PRE | 423 | 58.9 | 33.1 | 29.1 | 180 |
| 14 | PRE | 398 | 53.1 | 30 | 27.3 | 174 |
| 14 | 2HR | 412 | 74.7 | 49 | 27 | 176 |
| 14 | 4HR | 406 | 166 | 124 | 56.9 | 382 |
| 14 | 6HR | 393 | 162 | 119 | 51.9 | 337 |
| 14 | 8HR | 411 | 166 | 130 | 73.2 | 423 |
| 14 | 12HR | 417 | 132 | 92.1 | 63.7 | 400 |

Table 13g-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 09

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 374 | 59.6 | 35.5 | 34.4 | 252 |
| 16 | PRE | 421 | 62.3 | 37.8 | 42.1 | 289 |
| 17 | PRE | 368 | 68.6 | 41.2 | 31.7 | 264 |
| 18 | PRE | 427 | 81.9 | 54.1 | 39.1 | 300 |
| 19 | PRE | 427 | 164 | 120 | 53.3 | 386 |
| 20 | PRE | 440 | 234 | 166 | 47.7 | 312 |
| 21 | PRE | 433 | 221 | 155 | 66.4 | 384 |
| 21 | 2HR | 416 | 111 | 73.3 | 59.8 | 386 |
| 21 | 4HR | 438 | 91.2 | 55.6 | 54.5 | 393 |
| 21 | 6HR | 438 | 42.5 | 25.4 | 45.6 | 313 |
| 21 | 8HR | 410 | 58.1 | 36.8 | 42.4 | 364 |
| 21 | 12HR | 409 | 86.4 | 60.2 | 42.4 | 282 |
| 22 | PRE | | | | | |
| 25 | PRE | 432 | 42 | 20.6 | 30.2 | 227 |
| 29 | PRE | 419 | 58.4 | 32.8 | 44.8 | 263 |
| 32 | PRE | 415 | 56.5 | 34.3 | 35 | 251 |
| 33 | PRE | 470 | 54.9 | 29.4 | 19.9 | 147 |
| 36 | PRE | 387 | 46 | 29.9 | 19 | 126 |
| 39 | PRE | 391 | 104 | 68.9 | 30.8 | 227 |
| 42 | PRE | 417 | 81 | 50.9 | 36.8 | 255 |
| 42 | .5HR | 413 | 88 | 52.6 | 19.3 | 139 |
| 42 | 1HR | 413 | 120 | 73.2 | 37.1 | 256 |
| 42 | 2HR | 419 | 90.9 | 49.6 | 35 | 181 |
| 42 | 3HR | 424 | 72.9 | 43.2 | 32 | 207 |
| 42 | 4HR | 420 | 70.8 | 40.4 | 32.3 | 217 |
| 42 | 6HR | 418 | 54.9 | 29.4 | 30.5 | 222 |
| 42 | 8HR | 413 | 37.3 | 21.1 | 28.2 | 205 |
| 42 | 10HR | | | | | |
| 42 | 12HR | 404 | 25.8 | 15 | | 113 |
| 43 | AM | 454 | 17.8 | | | 73.5 |
| 44 | AM | 384 | 22 | 12.2 | | 73.5 |
| 45 | AM | 433 | 20.1 | 10.7 | | 42.2 |
| 48 | AM | 367 | 13.2 | 56.5 | | 22 |
| 51 | AM | 388 | | 44.8 | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13h-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 10

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 398 | | | | |
| 1 | .5HR | 392 | | | | |
| 1 | 1HR | 400 | | | | |
| 1 | 2HR | 402 | 19.6 | 28.8 | | |
| 1 | 3HR | 409 | 63.2 | 72.8 | | 29.3 |
| 1 | 4HR | 399 | 103 | 88.5 | 15.1 | 31 |
| 1 | 6HR | 395 | 86.9 | 66 | 16.5 | 33.7 |
| 1 | 8HR | 396 | 75.5 | 61.7 | 16.7 | 33.7 |
| 1 | 10HR | 406 | 58.1 | 56.2 | | 32.2 |
| 1 | 12HR | 400 | 43.5 | 47.6 | | 23 |
| 2 | PRE | 377 | 23.3 | 21.4 | | 20.4 |
| 3 | PRE | 404 | 20 | 12.4 | | 33.5 |
| 4 | PRE | 404 | 28.4 | 23.3 | 18.4 | 45.9 |
| 4 | 2HR | 413 | 32.9 | 30 | 19.2 | 51.8 |
| 4 | 4HR | 412 | 70.9 | 56.9 | 19.4 | 70.1 |
| 4 | 6HR | 405 | 63.2 | 46.7 | 20.2 | 66.8 |
| 4 | 8HR | 412 | 49.2 | 37.1 | 24.8 | 73.1 |
| 4 | 12HR | 414 | 34.1 | 23 | 24.2 | 68.7 |
| 5 | PRE | 412 | 24.3 | 15.4 | 21.7 | 71.4 |
| 6 | PRE | 409 | 20.5 | 16.5 | 19.2 | 71 |
| 7 | PRE | 410 | 19.8 | 14.2 | | 51 |
| 7 | 2HR | 419 | 43.5 | 37.5 | | 60 |
| 7 | 4HR | 405 | 63.3 | 54.6 | 19 | 79 |
| 7 | 6HR | 399 | 65.4 | 63.9 | 18.8 | 70.3 |
| 7 | 8HR | 418 | 51.7 | 43.9 | 16.5 | 67.4 |
| 7 | 12HR | 406 | 31.4 | 25.1 | | 54.3 |
| 8 | PRE | 414 | 29.1 | 21.4 | 15.3 | 61.1 |
| 9 | PRE | 414 | 81.7 | 50.4 | 28.8 | 104 |
| 10 | PRE | 438 | 62 | 45.4 | 22.1 | 103 |
| 11 | PRE | 420 | 45.1 | 32.1 | 33.5 | 137 |
| 12 | PRE | 418 | 58.1 | 34.7 | 22.1 | 90.6 |
| 13 | PRE | 406 | 47.6 | 28 | 20.3 | 81.9 |
| 14 | PRE | 402 | 56.2 | 45.2 | 18 | 73.7 |
| 14 | 2HR | 406 | 167 | 140 | 20.9 | 96.9 |
| 14 | 4HR | 442 | 334 | 359 | 36.8 | 132 |
| 14 | 6HR | 439 | 259 | 192 | 40.8 | 150 |
| 14 | 8HR | 450 | 283 | 196 | 48.3 | 156 |
| 14 | 12HR | 420 | 178 | 109 | 40.2 | 152 |

Table 13h-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 10

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 440 | 98.6 | 57.7 | 45.3 | 207 |
| 16 | PRE | 420 | 83.6 | 45.4 | 41.4 | 202 |
| 17 | PRE | 415 | 65.9 | 37.4 | 33.5 | 200 |
| 18 | PRE | 403 | 224 | 200 | 43.7 | 245 |
| 19 | PRE | 433 | 359 | 333 | 47.4 | 209 |
| 20 | PRE | 451 | 278 | 192 | 55.5 | 213 |
| 21 | PRE | 429 | 254 | 172 | 61.1 | 255 |
| 21 | 2HR | 446 | 173 | 109 | 44.7 | 200 |
| 21 | 4HR | 416 | 95.1 | 51.1 | 38.5 | 212 |
| 21 | 6HR | 405 | 98.4 | 62.7 | 46.4 | 232 |
| 21 | 8HR | 432 | 87.9 | 53.5 | 36 | 216 |
| 21 | 12HR | 414 | 136 | 82.1 | 43.5 | 215 |
| 22 | PRE | | | | | |
| 25 | PRE | 377 | 118 | 64.5 | 57.4 | 287 |
| 29 | PRE | 414 | 94.6 | 47.4 | 50.3 | 301 |
| 32 | PRE | 413 | 67.8 | 35.6 | 26.1 | 178 |
| 33 | PRE | 373 | 83.7 | 44 | 31.7 | 236 |
| 36 | PRE | 392 | 54.5 | 37.8 | 19.8 | 151 |
| 39 | PRE | 379 | 165 | 124 | 54.9 | 403 |
| 42 | PRE | 445 | 435 | 468 | 44.1 | 481 |
| 42 | .5HR | 436 | 318 | 261 | 48.7 | 324 |
| 42 | 1HR | 411 | 303 | 234 | 68.2 | 431 |
| 42 | 2HR | 410 | 204 | 150 | 47.4 | 326 |
| 42 | 3HR | 419 | 259 | 184 | 55.9 | 340 |
| 42 | 4HR | 418 | 203 | 128 | 56.3 | 314 |
| 42 | 6HR | 430 | 127 | 80.5 | 60.3 | 420 |
| 42 | 8HR | 415 | 58.9 | 33.3 | 31.5 | 255 |
| 42 | 10HR | | | | | |
| 42 | 12HR | 406 | 43.2 | 37 | | 198 |
| 43 | AM | 411 | 36.1 | 30.9 | | 168 |
| 44 | AM | 404 | 24.7 | 23.4 | | 106 |
| 45 | AM | | | | | |
| 48 | AM | | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13I-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 11

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 412 | | | | |
| 1 | .5HR | 421 | | | | |
| 1 | 1HR | 414 | 17.9 | 16.9 | | |
| 1 | 2HR | 409 | 34.8 | 27.4 | | |
| 1 | 3HR | 455 | 31.2 | 23 | | |
| 1 | 4HR | 474 | 80 | 50.9 | 24.2 | 45.7 |
| 1 | 6HR | 414 | 42.2 | 24.8 | | 20.8 |
| 1 | 8HR | 414 | 41 | 22.9 | 17.2 | 31 |
| 1 | 10HR | 415 | 39.9 | 23 | 16.9 | 31.3 |
| 1 | 12HR | 416 | 28.4 | 16.5 | 17.9 | 35.7 |
| 2 | PRE | 423 | 17.1 | | 16.2 | 31.5 |
| 3 | PRE | 444 | 83.1 | 47.5 | 44 | 100 |
| 4 | PRE | 435 | 44.8 | 22.1 | 40.9 | 96.3 |
| 4 | 2HR | 425 | 63.4 | 44.6 | 41.4 | 95 |
| 4 | 4HR | 437 | 134 | 96.9 | 59.7 | 164 |
| 4 | 6HR | 416 | 103 | 69.9 | 53.8 | 137 |
| 4 | 8HR | 448 | 99.4 | 65.6 | 51.9 | 137 |
| 4 | 12HR | 439 | 79.3 | 48.7 | 45.1 | 125 |
| 5 | PRE | 439 | 48.5 | 29.5 | 41.6 | 103 |
| 6 | PRE | 444 | 57.6 | 34.4 | 46.8 | 139 |
| 7 | PRE | 421 | 32.5 | 21.6 | 29.8 | 84.8 |
| 7 | 2HR | 434 | 55.4 | 42.4 | 30.6 | 101 |
| 7 | 4HR | 424 | 109 | 79.1 | 47.5 | 142 |
| 7 | 6HR | 429 | 85.8 | 56.7 | 36.2 | 103 |
| 7 | 8HR | 437 | 75 | 49.1 | 33.6 | 94.8 |
| 7 | 12HR | 410 | 59.3 | 37.5 | 32.9 | 93.4 |
| 8 | PRE | 424 | 33.3 | 20 | 32 | 96.9 |
| 9 | PRE | 423 | 43.5 | 25.8 | 35.7 | 126 |
| 10 | PRE | 430 | 34.1 | 21.1 | 25.6 | 86.6 |
| 11 | PRE | 427 | 41.7 | 26.2 | 26.6 | 97.4 |
| 12 | PRE | 412 | 41.3 | 23.7 | 27.7 | 102 |
| 13 | PRE | 407 | 58.5 | 36.4 | 42.1 | 167 |
| 14 | PRE | 438 | 43.9 | 31.3 | 32 | 135 |
| 14 | 2HR | 409 | 67.2 | 52.7 | 25.9 | 102 |
| 14 | 4HR | 447 | 216 | 205 | 41.1 | 157 |
| 14 | 6HR | 436 | 302 | 264 | 47.5 | 167 |
| 14 | 8HR | 439 | 324 | 269 | 41.8 | 133 |
| 14 | 12HR | 452 | 187 | 159 | 50.3 | 155 |

Table 13I-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 11

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 431 | 73.9 | 41.7 | 44.4 | 193 |
| 16 | PRE | 458 | 60.5 | 30.9 | 33.6 | 137 |
| 17 | PRE | 451 | 65.6 | 34.6 | 27.7 | 130 |
| 18 | PRE | 454 | 67.1 | 40.4 | 31.3 | 118 |
| 19 | PRE | 441 | 86.2 | 58.9 | 27 | 98.7 |
| 20 | PRE | 450 | 127 | 87.4 | 39.3 | 195 |
| 21 | PRE | 483 | 96.8 | 65.6 | 32.7 | 131 |
| 21 | 2HR | 438 | 81.4 | 50.8 | 39.3 | 176 |
| 21 | 4HR | 440 | 56.1 | 29.9 | 27.5 | 120 |
| 21 | 6HR | 474 | 54.1 | 29.1 | 32.9 | 125 |
| 21 | 8HR | 441 | 46.4 | 25.8 | 28.9 | 150 |
| 21 | 12HR | 438 | 63.4 | 37.8 | 35.7 | 154 |
| 22 | PRE | | | | | |
| 25 | PRE | | | | | |
| 29 | PRE | 452 | 72.3 | 42 | 58.1 | 201 |
| 32 | PRE | 473 | 54.5 | 30.1 | 39.5 | 201 |
| 33 | PRE | 434 | 49.4 | 27.3 | 39.7 | 166 |
| 36 | PRE | 418 | 60.3 | 39.6 | 48.2 | 203 |
| 39 | PRE | 451 | 142 | 115 | 66.1 | 319 |
| 42 | PRE | 491 | 176 | 127 | 65.6 | 307 |
| 42 | .5HR | 476 | 205 | 147 | 74 | 390 |
| 42 | 1HR | 478 | 135 | 93.6 | 49.8 | 233 |
| 42 | 2HR | 471 | 111 | 67.8 | 51.9 | 230 |
| 42 | 3HR | 425 | 155 | 98.2 | 77.6 | 367 |
| 42 | 4HR | 450 | 92.9 | 55.2 | 46.8 | 251 |
| 42 | 6HR | 434 | 54.2 | 31.5 | 45.4 | 225 |
| 42 | 8HR | 427 | 43.6 | 24.3 | 35.7 | 204 |
| 42 | 10HR | 463 | 38.5 | 22.3 | 24.4 | 162 |
| 42 | 12HR | | | | | |
| 43 | AM | | | | | |
| 44 | AM | | | | | |
| 45 | AM | | | | | |
| 48 | AM | | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13j-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 14

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 403 | | | | |
| 1 | .5HR | 406 | | | | |
| 1 | 1HR | 399 | | | | |
| 1 | 2HR | 421 | 11.2 | | | |
| 1 | 3HR | 416 | 24.8 | 13.7 | | |
| 1 | 4HR | 389 | 44 | 19.5 | | 17.1 |
| 1 | 6HR | 385 | 49.2 | 22.3 | | 15.6 |
| 1 | 8HR | 426 | 50.4 | 20.7 | | 19.1 |
| 1 | 10HR | 419 | 50.7 | 19.7 | | 22.6 |
| 1 | 12HR | 426 | 34.5 | 12.7 | | 22.3 |
| 2 | PRE | 420 | 18.9 | | | 18.8 |
| 3 | PRE | 403 | 16.9 | | | 19.4 |
| 4 | PRE | 408 | 28.4 | | | 33.3 |
| 4 | 2HR | 412 | 39.8 | 19.2 | | 38.6 |
| 4 | 4HR | 410 | 48.7 | 23.7 | 15.8 | 59.8 |
| 4 | 6HR | 403 | 68 | 29.1 | 15.8 | 59.5 |
| 4 | 8HR | 407 | 44.8 | 15 | | 33.6 |
| 4 | 12HR | 398 | 38.6 | 13.2 | | 45.8 |
| 5 | PRE | 404 | 28.7 | 10.3 | | 29.6 |
| 6 | PRE | 419 | 47.1 | 17.3 | | 83.3 |
| 7 | PRE | 412 | 52.5 | 17.6 | | 53.4 |
| 7 | 2HR | 413 | 40.9 | 23.9 | | 59.2 |
| 7 | 4HR | 416 | 66 | 27 | | 70.5 |
| 7 | 6HR | 412 | 73.3 | 29.6 | 18.2 | 84.7 |
| 7 | 8HR | 420 | 53.3 | 19.9 | | 63 |
| 7 | 12HR | 420 | 45.6 | 13.6 | | 51.1 |
| 8 | PRE | 413 | 39.2 | 12.9 | | 55.1 |
| 9 | PRE | 413 | 50.3 | 16.9 | 15.6 | 72 |
| 10 | PRE | 424 | 96.8 | 33.6 | 26.5 | 116 |
| 11 | PRE | 428 | 99.7 | 33.3 | 20.5 | 97.8 |
| 12 | PRE | 421 | 99.5 | 30 | 28.6 | 155 |
| 13 | PRE | 418 | 71.6 | 23.9 | 25.2 | 196 |
| 14 | PRE | 413 | 73.3 | 22.8 | 28.4 | 195 |
| 14 | 2HR | 419 | 99.8 | 40.4 | 34.4 | 298 |
| 14 | 4HR | 413 | 168 | 82.6 | 50 | 320 |
| 14 | 6HR | 413 | 176 | 87.9 | 44 | 317 |
| 14 | 8HR | 405 | 182 | 84 | 55.5 | 374 |
| 14 | 12HR | 417 | 104 | 42 | 39.6 | 299 |

Table 13j-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 14

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 422 | 91.6 | 29.1 | 35.2 | 320 |
| 16 | PRE | 421 | 90 | 27.6 | 31.2 | 303 |
| 17 | PRE | 421 | 60.4 | 18.4 | 20 | 199 |
| 18 | PRE | 415 | 156 | 69.5 | 37.8 | 336 |
| 19 | PRE | 413 | 154 | 65.1 | 31.2 | 233 |
| 20 | PRE | 420 | 140 | 62.2 | 29.9 | 244 |
| 21 | PRE | 414 | 99.8 | 40.9 | 23.1 | 176 |
| 21 | 2HR | 421 | 86.2 | 29.1 | 22.1 | 161 |
| 21 | 4HR | 416 | 74.7 | 22.6 | 29.4 | 292 |
| 21 | 6HR | 444 | 126 | 38.3 | 32.8 | 339 |
| 21 | 8HR | 450 | 272 | 91.3 | 56.3 | 460 |
| 21 | 12HR | 430 | 215 | 72.6 | 38 | 311 |
| 22 | PRE | | | | | |
| 25 | PRE | 448 | 206 | 61.6 | 48.5 | 401 |
| 29 | PRE | 438 | 223 | 70.6 | 54.5 | 405 |
| 32 | PRE | | | | | |
| 33 | PRE | | | | | |
| 36 | PRE | | | | | |
| 39 | PRE | | | | | |
| 42 | PRE | | | | | |
| 42 | .5HR | | | | | |
| 42 | 1HR | | | | | |
| 42 | 2HR | | | | | |
| 42 | 3HR | | | | | |
| 42 | 4HR | | | | | |
| 42 | 6HR | | | | | |
| 42 | 8HR | | | | | |
| 42 | 10HR | | | | | |
| 42 | 12HR | | | | | |
| 43 | AM | | | | | |
| 44 | AM | | | | | |
| 45 | AM | | | | | |
| 48 | AM | | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13k-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 15

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 401 | | | | |
| 1 | .5HR | 388 | | | | |
| 1 | 1HR | 349 | | | | |
| 1 | 2HR | 395 | 23.9 | 19.6 | | |
| 1 | 3HR | 374 | 28.6 | 19.9 | | |
| 1 | 4HR | 395 | 44 | 26.9 | | 15.7 |
| 1 | 6HR | 397 | 43.7 | 23.9 | | |
| 1 | 8HR | 392 | 38.6 | 20.7 | | |
| 1 | 10HR | 388 | 31.9 | 14.1 | | |
| 1 | 12HR | 388 | 22.3 | | | |
| 2 | PRE | 399 | 13 | | | |
| 3 | PRE | 405 | 39.1 | 18.8 | | 23.9 |
| 4 | PRE | 381 | 33.7 | 14 | | 50.3 |
| 4 | 2HR | 416 | 61.1 | 37.1 | | 58.1 |
| 4 | 4HR | 396 | 70.6 | 39.7 | 18 | 88.6 |
| 4 | 6HR | 383 | 70.2 | 36.5 | 22.3 | 108 |
| 4 | 8HR | 401 | 59.7 | 28.3 | 20.9 | 89.7 |
| 4 | 12HR | 381 | 47.3 | 21 | | 68.8 |
| 5 | PRE | 388 | 33.2 | 12.2 | | 41 |
| 6 | PRE | 404 | 35.1 | 13 | 16.9 | 89 |
| 7 | PRE | 398 | 34.6 | 12.2 | 16.3 | 97.5 |
| 7 | 2HR | 383 | 58.5 | 33.8 | 15.3 | 87.9 |
| 7 | 4HR | 395 | 100 | 57.7 | 20.9 | 149 |
| 7 | 6HR | 365 | 98.2 | 54.4 | 20 | 112 |
| 7 | 8HR | 394 | 72.6 | 36.9 | | 53.8 |
| 7 | 12HR | 371 | 68.8 | 27.5 | | 49.2 |
| 8 | PRE | 397 | 34.8 | 14.4 | | 83.6 |
| 9 | PRE | 396 | 30.4 | 13.3 | | 55.1 |
| 10 | PRE | 401 | 47.1 | 22.1 | 20 | 120 |
| 11 | PRE | 404 | 50.4 | 23.7 | 16.7 | 102 |
| 12 | PRE | 388 | 49.7 | 22.8 | 20.2 | 135 |
| 13 | PRE | 401 | 35.1 | 17.7 | 16.9 | 110 |
| 14 | PRE | 396 | 53.1 | 24.8 | 19.8 | 154 |
| 14 | 2HR | 398 | 94.8 | 61.6 | 27.5 | 186 |
| 14 | 4HR | 430 | 107 | 65.2 | 36.2 | 221 |
| 14 | 6HR | 410 | 138 | 75.5 | 22.3 | 137 |
| 14 | 8HR | 409 | 121 | 64.9 | 30.8 | 180 |
| 14 | 12HR | 398 | 91.5 | 41.1 | 24.4 | 169 |

Table 13k-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 15

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 409 | 51.6 | 23.1 | 21.3 | 167 |
| 16 | PRE | 397 | 53.8 | 29.5 | 21.3 | 188 |
| 17 | PRE | 392 | 38.2 | 17 | | 137 |
| 18 | PRE | 401 | 85.4 | 49.4 | 20.7 | 180 |
| 19 | PRE | 435 | 142 | 94.3 | 31.8 | 250 |
| 20 | PRE | 416 | 145 | 92.5 | 22.3 | 173 |
| 21 | PRE | 409 | 125 | 76.3 | 31.2 | 251 |
| 21 | 2HR | 403 | 89.6 | 50.1 | 20.9 | 178 |
| 21 | 4HR | 394 | 49.7 | 24.8 | 28.7 | 221 |
| 21 | 6HR | 423 | 40.1 | 18.5 | 22.9 | 161 |
| 21 | 8HR | 418 | 86.2 | 43.9 | 42 | 319 |
| 21 | 12HR | 402 | 94.5 | 48.7 | 42 | 346 |
| 22 | PRE | | | | | |
| 25 | PRE | 407 | 77.9 | 34.5 | 33.1 | 332 |
| 29 | PRE | 404 | 75.4 | 36.5 | 36.4 | 342 |
| 32 | PRE | 406 | 76.1 | 35.8 | | 182 |
| 33 | PRE | 393 | 90.5 | 44.8 | 20.2 | 242 |
| 36 | PRE | 410 | 100 | 54.1 | 31.2 | 375 |
| 39 | PRE | 392 | 108 | 56.8 | 18.8 | 199 |
| 42 | PRE | 414 | 151 | 86 | 52.3 | 514 |
| 42 | .5HR | 389 | 138 | 73.5 | 39.1 | 372 |
| 42 | 1HR | 408 | 123 | 64.4 | 19.6 | 163 |
| 42 | 2HR | 404 | 124 | 66.2 | 26.7 | 270 |
| 42 | 3HR | 402 | 114 | 58.1 | 29.1 | 284 |
| 42 | 4HR | 420 | 128 | 66.9 | 38.3 | 326 |
| 42 | 6HR | 415 | 89.1 | 42.7 | 34.3 | 406 |
| 42 | 8HR | 401 | 65.8 | 32 | 20.9 | 270 |
| 42 | 10HR | 395 | 46.2 | 22.1 | 17.3 | 272 |
| 42 | 12HR | 389 | 33 | 12.8 | | 188 |
| 43 | AM | 399 | 26.2 | | | 106 |
| 44 | AM | 347 | 31.5 | 12.4 | | 72.2 |
| 45 | AM | 383 | 20.2 | | | 26.9 |
| 48 | AM | 432 | 22.1 | | | |
| 51 | AM | 397 | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13L-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 16

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 380 | | | | |
| 1 | .5HR | 396 | | | | |
| 1 | 1HR | 393 | | | | |
| 1 | 2HR | 390 | 18.1 | 12.9 | | |
| 1 | 3HR | 400 | 38.7 | 25.9 | | |
| 1 | 4HR | 400 | 40.3 | 24.4 | | |
| 1 | 6HR | 394 | 21.7 | 11.1 | | |
| 1 | 8HR | 374 | 19.8 | | | |
| 1 | 10HR | 400 | 20.1 | 10.2 | | 16.6 |
| 1 | 12HR | 400 | 20.6 | | | 19.5 |
| 2 | PRE | 392 | 11 | | | 18.5 |
| 3 | PRE | 382 | 18.9 | | | 49.1 |
| 4 | PRE | 399 | 28.5 | 13.6 | | 78.1 |
| 4 | 2HR | 395 | 51.2 | 30.4 | | 85.1 |
| 4 | 4HR | 396 | 94.1 | 54.3 | 18.7 | 132 |
| 4 | 6HR | 399 | 68.6 | 37.2 | 18.2 | 99.5 |
| 4 | 8HR | 401 | 55.7 | 28.6 | | 77.5 |
| 4 | 12HR | 401 | 46.9 | 23.4 | 22.7 | 128 |
| 5 | PRE | 403 | 35.2 | 16.6 | 17.6 | 123 |
| 6 | PRE | 404 | 42.7 | 20.7 | 29.3 | 200 |
| 7 | PRE | 405 | 53.1 | 24.1 | 36.7 | 267 |
| 7 | 2HR | 404 | 83.3 | 50.3 | 35.6 | 238 |
| 7 | 4HR | 401 | 153 | 87.3 | 24.7 | 157 |
| 7 | 6HR | 400 | 189 | 105 | 20.7 | 146 |
| 7 | 8HR | 399 | 128 | 66.8 | 34.7 | 214 |
| 7 | 12HR | 407 | 87.3 | 43.7 | 35.6 | 254 |
| 8 | PRE | 406 | 49.1 | 23.4 | 27.6 | 226 |
| 9 | PRE | 405 | 57.5 | 26.1 | 32.7 | 256 |
| 10 | PRE | 400 | 55.4 | 24.9 | 41.6 | 335 |
| 11 | PRE | 408 | 58.5 | 27.9 | 31.6 | 292 |
| 12 | PRE | 397 | 57.1 | 28.7 | 31.6 | 290 |
| 13 | PRE | 411 | 67.5 | 29.4 | 33.3 | 317 |
| 14 | PRE | 402 | 64.8 | 27.9 | 32.5 | 334 |
| 14 | 2HR | 416 | 73.8 | 38.7 | 36.5 | 354 |
| 14 | 4HR | 403 | 107 | 57.6 | 52.2 | 462 |
| 14 | 6HR | 404 | 132 | 68.9 | 55.9 | 473 |
| 14 | 8HR | 403 | 90.9 | 46.8 | 48.7 | 430 |
| 14 | 12HR | 400 | 101 | 44.2 | 48.7 | 430 |

Table 13L-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 16

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 403 | 81.8 | 35.1 | 49.6 | 561 |
| 16 | PRE | 411 | 94 | 40.9 | 51.9 | 588 |
| 17 | PRE | 404 | 97.7 | 38.6 | 43.3 | 521 |
| 18 | PRE | 391 | 110 | 58.3 | 43.9 | 587 |
| 19 | PRE | 421 | 219 | 125 | 45 | 548 |
| 20 | PRE | 414 | 215 | 120 | 45.6 | 532 |
| 21 | PRE | 410 | 152 | 80.8 | 68.7 | 715 |
| 21 | 2HR | 411 | 151 | 69.6 | 51.6 | 492 |
| 21 | 4HR | 400 | 91.5 | 39.2 | 37.6 | 552 |
| 21 | 6HR | 420 | 85.9 | 36.1 | 44.2 | 569 |
| 21 | 8HR | 426 | 69.8 | 30.7 | 34.7 | 393 |
| 21 | 12HR | 434 | 138 | 66.9 | 41.6 | 510 |
| 22 | PRE | | | | | |
| 25 | PRE | 424 | 152 | 68.4 | 47.9 | 497 |
| 29 | PRE | 427 | 242 | 115 | 73 | 594 |
| 32 | PRE | 438 | 87.7 | 39.7 | 28.2 | 335 |
| 33 | PRE | 420 | 108 | 47.8 | 31.9 | 375 |
| 36 | PRE | 407 | 90.5 | 41.2 | 32.2 | 344 |
| 39 | PRE | 403 | 120 | 63.3 | 32.2 | 381 |
| 42 | PRE | 433 | 208 | 114 | 47.9 | 524 |
| 42 | .5HR | 408 | 242 | 137 | 43.3 | 480 |
| 42 | 1HR | 416 | 183 | 96.5 | 28.2 | 383 |
| 42 | 2HR | 414 | 143 | 71.4 | 33 | 363 |
| 42 | 3HR | 410 | 178 | 86.3 | 42.7 | 484 |
| 42 | 4HR | 415 | 119 | 57.8 | 33.3 | 368 |
| 42 | 6HR | 419 | 114 | 49.6 | 28.5 | 377 |
| 42 | 8HR | 422 | 114 | 46.6 | 41 | 563 |
| 42 | 10HR | | | | | |
| 42 | 12HR | | | | | |
| 43 | AM | | | | | |
| 44 | AM | | | | | |
| 45 | AM | | | | | |
| 48 | AM | 399 | 21.1 | | | 38.9 |
| 51 | AM | 416 | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13m-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 18

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 403 | | | | |
| 1 | .5HR | 394 | | | | |
| 1 | 1HR | 400 | | | | |
| 1 | 2HR | 409 | 24.1 | 20.5 | 28.4 | |
| 1 | 3HR | 403 | 82.5 | 75.1 | 16.5 | 22.6 |
| 1 | 4HR | 403 | 147 | 128 | 15.5 | 22.6 |
| 1 | 6HR | 402 | 105 | 83.2 | 16.3 | 23.3 |
| 1 | 8HR | 403 | 85.9 | 58.9 | 18.5 | 31.3 |
| 1 | 10HR | 409 | 76.2 | 49.3 | 15.5 | 32.7 |
| 1 | 12HR | 402 | 61.2 | 38.3 | 16.3 | 28.9 |
| 2 | PRE | 409 | 60.6 | 26.6 | 20.4 | 95.7 |
| 3 | PRE | 411 | 29.3 | 15 | | 24.8 |
| 4 | PRE | 416 | 67.1 | 31.1 | 23.4 | 124 |
| 4 | 2HR | 412 | 74.3 | 42.3 | 19.5 | 116 |
| 4 | 4HR | 413 | 116 | 74.2 | 25.4 | 138 |
| 4 | 6HR | 441 | 156 | 94.3 | 23.2 | 126 |
| 4 | 8HR | 411 | 114 | 64.4 | 19.5 | 91.6 |
| 4 | 12HR | 415 | 95.9 | 48 | 18.9 | 96.8 |
| 5 | PRE | 422 | 60.5 | 27.8 | 25.6 | 135 |
| 6 | PRE | 415 | 66 | 32.3 | 31.2 | 190 |
| 7 | PRE | 421 | 114 | 56.4 | 27.2 | 182 |
| 7 | 2HR | 410 | 82.4 | 45.2 | 26 | 153 |
| 7 | 4HR | 438 | 224 | 158 | 33.4 | 213 |
| 7 | 6HR | 435 | 226 | 153 | 28.2 | 191 |
| 7 | 8HR | 422 | 87.4 | 41.9 | 24.8 | 207 |
| 7 | 12HR | 421 | 141 | 78.4 | 26 | 153 |
| 8 | PRE | 418 | 87.9 | 41 | 28.6 | 204 |
| 9 | PRE | 451 | 82.2 | 35.8 | 27 | 235 |
| 10 | PRE | 422 | 91.2 | 41.2 | 32.8 | 235 |
| 11 | PRE | 416 | 85.4 | 37.1 | 39 | 239 |
| 12 | PRE | 419 | 103 | 43.4 | 38.2 | 299 |
| 13 | PRE | 440 | 85 | 37.1 | 26.4 | 265 |
| 14 | PRE | 430 | 87.9 | 36.8 | 28.4 | 267 |
| 14 | 2HR | 425 | 171 | 102 | 35 | 222 |
| 14 | 4HR | 428 | 166 | 107 | 37.6 | 293 |
| 14 | 6HR | 425 | 149 | 95.6 | 30.2 | 306 |
| 14 | 8HR | 420 | 118 | 67.1 | 26.4 | 267 |
| 14 | 12HR | 428 | 125 | 62.6 | 33.8 | 218 |

Table 13m-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 18

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 452 | 86.5 | 35.4 | 28.4 | 216 |
| 16 | PRE | 432 | 81.3 | 33.9 | 28.2 | 219 |
| 17 | PRE | 426 | 90.8 | 36.8 | 27.8 | 202 |
| 18 | PRE | 414 | 113 | 57.9 | 31.8 | 254 |
| 19 | PRE | 437 | 147 | 82.6 | 23.4 | 245 |
| 20 | PRE | 446 | 186 | 102 | 31.4 | 227 |
| 21 | PRE | 428 | 166 | 83.1 | 30.8 | 253 |
| 21 | 2HR | 428 | 116 | 52.7 | 23.2 | 211 |
| 21 | 4HR | 431 | 93 | 37.1 | 27.6 | 197 |
| 21 | 6HR | 450 | 56.7 | 24.7 | 17.7 | 212 |
| 21 | 8HR | 426 | 70.1 | 32.7 | 19.7 | 182 |
| 21 | 12HR | 453 | 157 | 87.4 | 29.8 | 173 |
| 22 | PRE | | | | | |
| 25 | PRE | | | | | |
| 29 | PRE | | | | | |
| 32 | PRE | 475 | 213 | 112 | 39.2 | 384 |
| 33 | PRE | 462 | 215 | 127 | 37.8 | 389 |
| 36 | PRE | 456 | 201 | 117 | 37.8 | 377 |
| 39 | PRE | 434 | 209 | 159 | 38.4 | 438 |
| 42 | PRE | 464 | 219 | 157 | 33.8 | 394 |
| 42 | .5HR | 454 | 293 | 204 | 33.6 | 393 |
| 42 | 1HR | 420 | 311 | 198 | 43.3 | 402 |
| 42 | 2HR | 415 | 260 | 166 | 37.8 | 352 |
| 42 | 3HR | 426 | 237 | 133 | 45.3 | 335 |
| 42 | 4HR | 428 | 247 | 128 | 32.8 | 353 |
| 42 | 6HR | 423 | 165 | 80 | 31.8 | 294 |
| 42 | 8HR | 445 | | | | |
| 42 | 10HR | 440 | 110 | 47.3 | 18.1 | 273 |
| 42 | 12HR | | 54.8 | 20.7 | 17.7 | 291 |
| 43 | AM | 424 | 58.9 | 21.7 | | 215 |
| 44 | AM | 419 | 42.3 | 20.2 | | 141 |
| 45 | AM | 415 | 42.7 | 17.3 | | 73.2 |
| 48 | AM | 416 | 27.7 | 14 | | 43.3 |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13n-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 19

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 395 | | | | |
| 1 | .5HR | 377 | | | | |
| 1 | 1HR | 366 | 26.6 | 23.2 | | |
| 1 | 2HR | 389 | 40.7 | 34.7 | 18.4 | |
| 1 | 3HR | 404 | 48 | 34.5 | 15.8 | |
| 1 | 4HR | 418 | 40.9 | 27.8 | | |
| 1 | 6HR | 402 | 60.4 | 37.4 | | 17.2 |
| 1 | 8HR | 402 | 37.8 | 20.8 | | 15.3 |
| 1 | 10HR | 405 | 45.2 | 24.7 | | 15.3 |
| 1 | 12HR | 404 | 34.3 | 19.2 | | 20.1 |
| 2 | PRE | 402 | 26.6 | 13.4 | 22 | 16.4 |
| 3 | PRE | 422 | 44.7 | 26.9 | | 33.6 |
| 4 | PRE | 410 | 50.4 | 29 | 15.5 | 40.2 |
| 4 | 2HR | 404 | 65 | 43.1 | 23.1 | 60 |
| 4 | 4HR | 409 | 151 | 115 | 23.6 | 62.2 |
| 4 | 6HR | 410 | 145 | 107 | | 65.6 |
| 4 | 8HR | 418 | 110 | 77.9 | 23.1 | 77 |
| 4 | 12HR | 404 | 66 | 44.2 | | 58.5 |
| 5 | PRE | 404 | 50.5 | 31.4 | | 66.9 |
| 6 | PRE | 404 | 52.5 | 31.6 | 15.5 | 88.6 |
| 7 | PRE | 403 | 53.6 | 27.8 | 15.8 | 99.5 |
| 7 | 2HR | | 104 | 78.8 | | 116 |
| 7 | 4HR | 403 | 155 | 121 | 17.2 | 115 |
| 7 | 6HR | 413 | 130 | 99.7 | | 107 |
| 7 | 8HR | 421 | 87.8 | 67.9 | | 49.5 |
| 7 | 12HR | 408 | 81.9 | 53 | | 68 |
| 8 | PRE | 403 | 61 | 46.6 | 15.3 | 120 |
| 9 | PRE | 409 | 44.5 | 32.1 | 15.5 | 119 |
| 10 | PRE | 406 | 64 | 45.2 | 27.7 | 157 |
| 11 | PRE | 407 | 57.5 | 37.7 | 20.5 | 147 |
| 12 | PRE | 408 | 60.9 | 44.1 | 25.3 | 187 |
| 13 | PRE | 393 | 57.8 | 37.7 | 22.2 | 176 |
| 14 | PRE | 416 | 59.9 | 35.7 | 23.9 | 222 |
| 14 | 2HR | | 98.1 | 68.9 | 26 | 242 |
| 14 | 4HR | | 210 | 131 | 17.7 | 223 |
| 14 | 6HR | | 197 | 120 | 18.9 | 151 |
| 14 | 8HR | | 164 | 103 | 24.8 | 179 |
| 14 | 12HR | | 121 | 65.7 | | 110 |

Table 13n-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 19

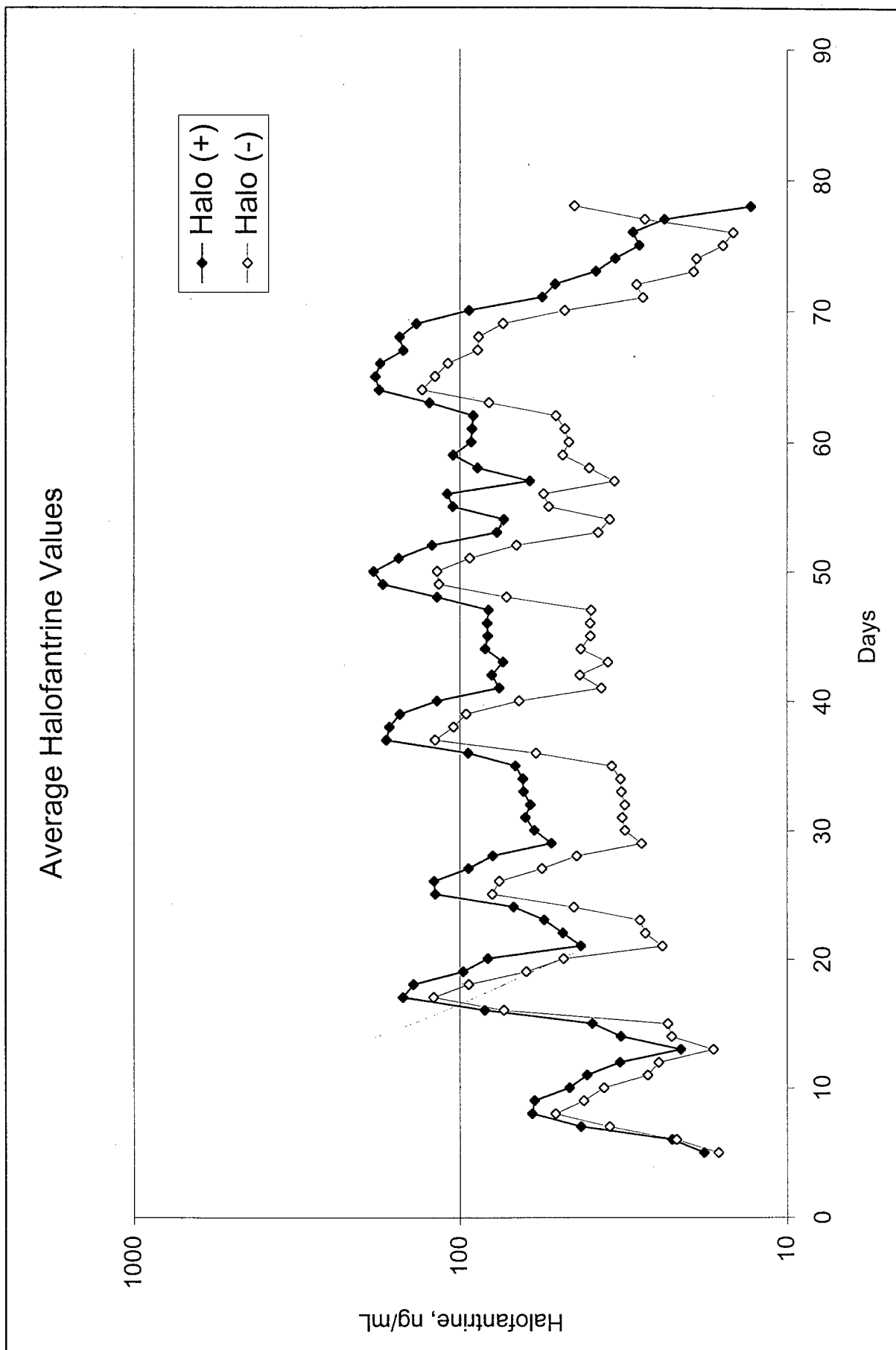
| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 411 | 86.7 | 45.6 | | 136 |
| 16 | PRE | 408 | 110 | 59.5 | | 127 |
| 17 | PRE | 396 | 89.9 | 66.8 | 20.1 | 183 |
| 18 | PRE | 404 | 51.1 | 41.9 | | 138 |
| 19 | PRE | 407 | 123 | 88.8 | | 109 |
| 20 | PRE | 405 | 76.3 | 73.7 | 26.2 | 248 |
| 21 | PRE | 405 | 77.9 | 59.4 | 34.3 | 285 |
| 21 | 2HR | 405 | 43.4 | 32.9 | 17 | 166 |
| 21 | 4HR | 410 | 33 | 22.6 | 19.8 | 186 |
| 21 | 6HR | 408 | 29.6 | 17.8 | | 188 |
| 21 | 8HR | 411 | 37.3 | 24.9 | 17.4 | 231 |
| 21 | 12HR | 442 | 40.1 | 27.1 | 18.9 | 217 |
| 22 | PRE | | 52 | 33.7 | 21.7 | 278 |
| 25 | PRE | 420 | 49.6 | 32.4 | 21.2 | 231 |
| 29 | PRE | 401 | 55.2 | 35.5 | 29.3 | 309 |
| 32 | PRE | 440 | 44.9 | 30 | | 179 |
| 33 | PRE | 409 | 45.9 | 29 | | 200 |
| 36 | PRE | 398 | 56.4 | 38.1 | 21.7 | 253 |
| 39 | PRE | 405 | 74.2 | 55 | 19.3 | 259 |
| 42 | PRE | 416 | 105 | 77 | 28.1 | 298 |
| 42 | .5HR | 406 | 106 | 70.3 | 23.9 | 278 |
| 42 | 1HR | 403 | 149 | 87.6 | 33.1 | 293 |
| 42 | 2HR | 410 | 101 | 63.5 | 33.8 | 271 |
| 42 | 3HR | 403 | 82.2 | 51.4 | 28.4 | 286 |
| 42 | 4HR | 410 | 80.6 | 46.3 | 23.1 | 268 |
| 42 | 6HR | 406 | 61.5 | 35.8 | 19.1 | 247 |
| 42 | 8HR | 398 | 40.8 | 22.1 | 16.7 | 214 |
| 42 | 10HR | 393 | 32 | 17.6 | 18.6 | 236 |
| 42 | 12HR | 406 | 27.8 | 11.8 | | 72.5 |
| 43 | AM | 415 | 19.5 | 10.5 | | 97.6 |
| 44 | AM | 367 | 15.8 | 10.2 | | 50 |
| 45 | AM | 401 | 13.1 | 11 | | 28 |
| 48 | AM | 403 | | | | |
| 51 | AM | | | | | |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |

Table 13o-1: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 20

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 1 | PRE | 422 | | | | |
| 1 | .5HR | 392 | | | | |
| 1 | 1HR | 415 | | | | |
| 1 | 2HR | 404 | | | | |
| 1 | 3HR | 402 | 14.8 | 13.8 | | 18.2 |
| 1 | 4HR | 402 | 24.2 | 18.1 | | 24.6 |
| 1 | 6HR | 398 | 19.5 | 12.9 | | 29.4 |
| 1 | 8HR | 398 | 12.7 | | | 29 |
| 1 | 10HR | 392 | | | | 30.3 |
| 1 | 12HR | 402 | | | | 31.7 |
| 2 | PRE | 4368 | | | 47.5 | 48.7 |
| 3 | PRE | 383 | | | | 48 |
| 4 | PRE | 397 | 15 | 11.5 | 23.6 | 105 |
| 4 | 2HR | 422 | 22.3 | 20.2 | 24 | 92.7 |
| 4 | 4HR | 404 | | | | 106 |
| 4 | 6HR | 403 | | | | 26 |
| 4 | 8HR | 413 | 36 | 26 | 32.3 | 139 |
| 4 | 12HR | 416 | 30.2 | 23.4 | 26 | 108 |
| 5 | PRE | 378 | 17.6 | 12.1 | 23.1 | 113 |
| 6 | PRE | 411 | 19.2 | 15.8 | 28.7 | 128 |
| 7 | PRE | 407 | 20.1 | 15.4 | 22.1 | 147 |
| 7 | 2HR | 411 | 30 | 23.9 | 29.1 | 159 |
| 7 | 4HR | 413 | 82.2 | 68.7 | 181 | 201 |
| 7 | 6HR | 408 | 39.5 | 32.9 | 28.5 | 155 |
| 7 | 8HR | 400 | 38.2 | 28.7 | 31.4 | 159 |
| 7 | 12HR | 405 | 30 | 17.7 | 25.8 | 131 |
| 8 | PRE | 411 | 24.2 | 20.5 | 28.7 | 169 |
| 9 | PRE | 407 | 23.2 | 20 | 29.4 | 169 |
| 10 | PRE | 413 | 28.2 | 17.9 | 26 | 184 |
| 11 | PRE | 409 | 23.1 | 17.9 | 31.8 | 184 |
| 12 | PRE | 425 | 20.4 | 14.7 | 29.4 | 183 |
| 13 | PRE | 415 | 29.3 | 23 | 34.1 | 190 |
| 14 | PRE | 411 | 29.7 | 22 | 26.9 | 183 |
| 14 | 2HR | 405 | 28.2 | 20.5 | 22.5 | 178 |
| 14 | 4HR | 410 | 47.1 | 36.9 | 40.7 | 176 |
| 14 | 6HR | 410 | 40.5 | 29 | 37 | 205 |
| 14 | 8HR | 426 | 55.2 | 42.1 | 36 | 209 |
| 14 | 12HR | 424 | 50 | 30.8 | 26.5 | 171 |

Table 13o-2: QTc Intervals and Halofantrine / Metabolite Concentrations for Subject 20

| <u>Day</u> | <u>Time</u> | <u>QTc</u> | <u>Halo +</u> | <u>Halo -</u> | <u>Metab +</u> | <u>Metab -</u> |
|------------|-------------|------------|---------------|---------------|----------------|----------------|
| 15 | PRE | 402 | | | | 20 |
| 16 | PRE | 409 | 32.9 | 23.2 | 21.1 | 162 |
| 17 | PRE | 410 | 36.5 | 20.4 | 21.9 | 134 |
| 18 | PRE | 411 | 41.6 | 33.8 | 27.9 | 176 |
| 19 | PRE | 417 | 83.8 | 59.7 | 33.3 | 192 |
| 20 | PRE | 417 | 51.7 | 34.8 | 26.5 | 163 |
| 21 | PRE | 432 | 56 | 37.3 | 25.6 | 170 |
| 21 | 2HR | 416 | 45.6 | 30.4 | 31 | 154 |
| 21 | 4HR | 424 | 19.2 | 13.1 | 20.7 | 153 |
| 21 | 6HR | 415 | 40.8 | 24.6 | 18.6 | 115 |
| 21 | 8HR | 448 | 78.4 | 57.1 | 39.1 | 201 |
| 21 | 12HR | 426 | 41.1 | 26 | 49 | 329 |
| 22 | PRE | | 35.9 | 22.5 | 42 | 264 |
| 25 | PRE | 427 | 36.9 | 18.1 | 53.1 | 420 |
| 29 | PRE | 421 | 22.4 | 14.4 | 43 | 385 |
| 32 | PRE | 438 | 33.8 | 17 | 28.5 | 304 |
| 33 | PRE | 437 | 27 | 17.2 | 33 | 330 |
| 36 | PRE | 425 | 40.8 | 24.8 | 40.9 | 389 |
| 39 | PRE | 428 | 35.7 | 26.4 | 38.7 | 346 |
| 42 | PRE | 442 | 71 | 57.5 | 49.3 | 424 |
| 42 | .5HR | 442 | 66.1 | 50.2 | 45.9 | 416 |
| 42 | 1HR | 435 | 80.3 | 53.4 | 41.1 | 386 |
| 42 | 2HR | 420 | 63.6 | 42.8 | 45.9 | 429 |
| 42 | 3HR | 416 | 57.3 | 37.3 | 42.7 | 383 |
| 42 | 4HR | 425 | 49.5 | 37.7 | 41.6 | 304 |
| 42 | 6HR | 414 | 34.3 | 22.3 | 33.2 | 309 |
| 42 | 8HR | 411 | 21.7 | 14.2 | 31.4 | 283 |
| 42 | 10HR | 411 | 17.4 | | 24.2 | 309 |
| 42 | 12HR | 412 | | | | 159 |
| 43 | AM | 414 | | | | 117 |
| 44 | AM | 407 | | | | |
| 45 | AM | 382 | | | 34.8 | 51.9 |
| 48 | AM | 409 | 18.9 | | 31.9 | 48.8 |
| 51 | AM | | 12.9 | | 29.4 | 64 |
| 54 | AM | | | | | |
| 57 | AM | | | | | |
| 72 | AM | | | | | |
| 180 | AM | | | | | |



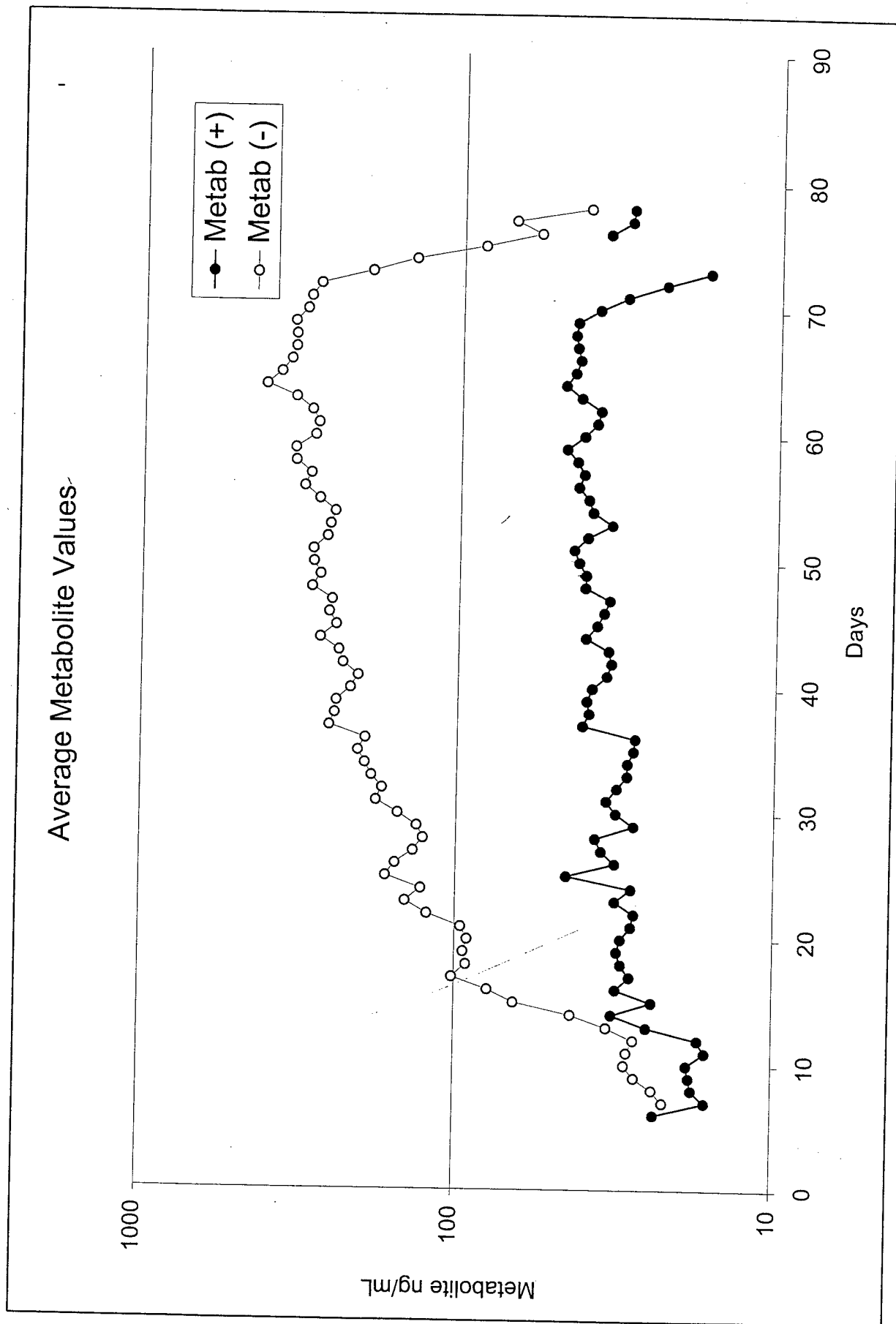


Figure 55a: Halofantrine and Metabolite Concentrations for Subject 01

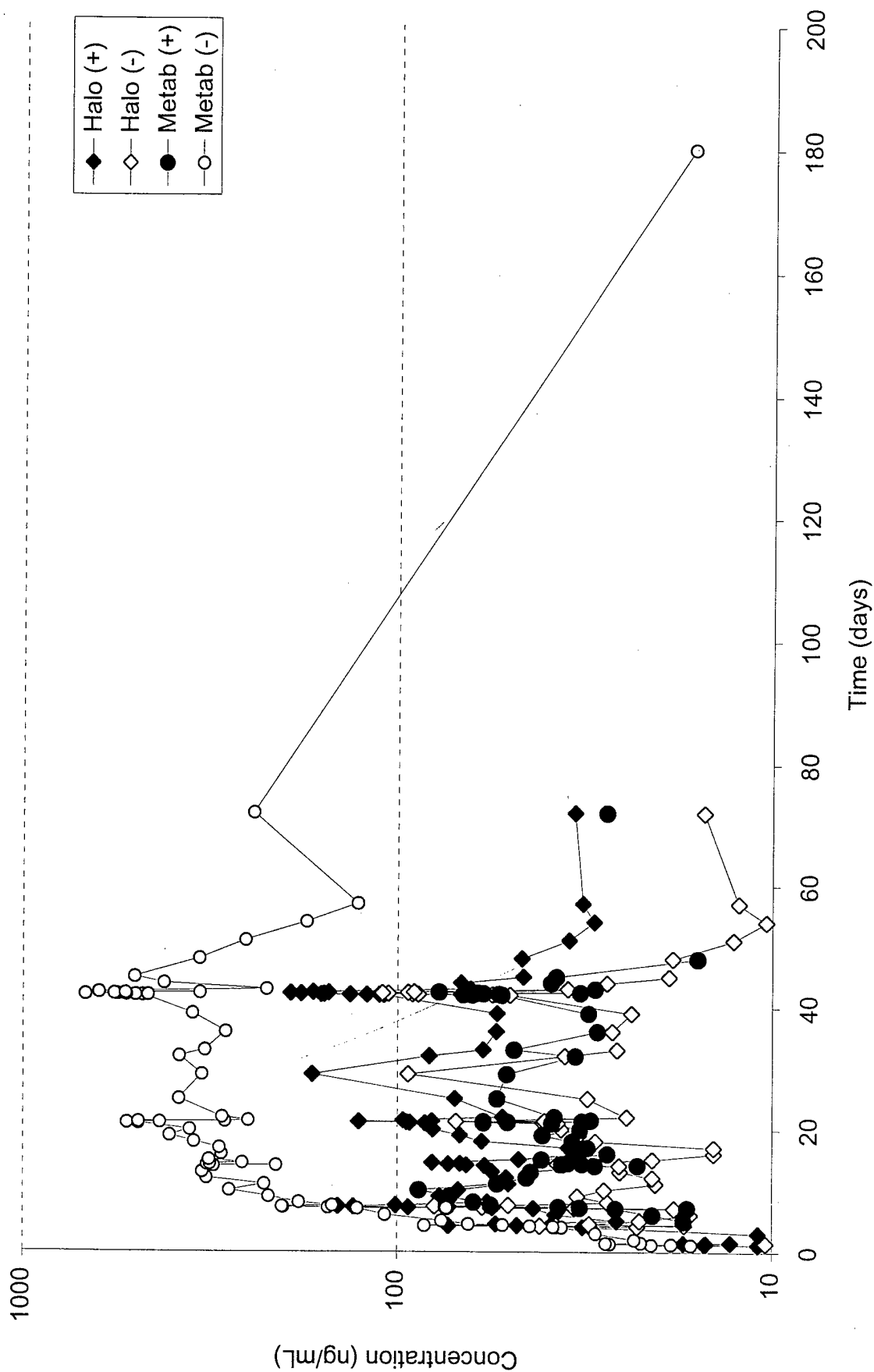


Figure 55b: Halofantrine and Metabolite Concentrations for Subject 02

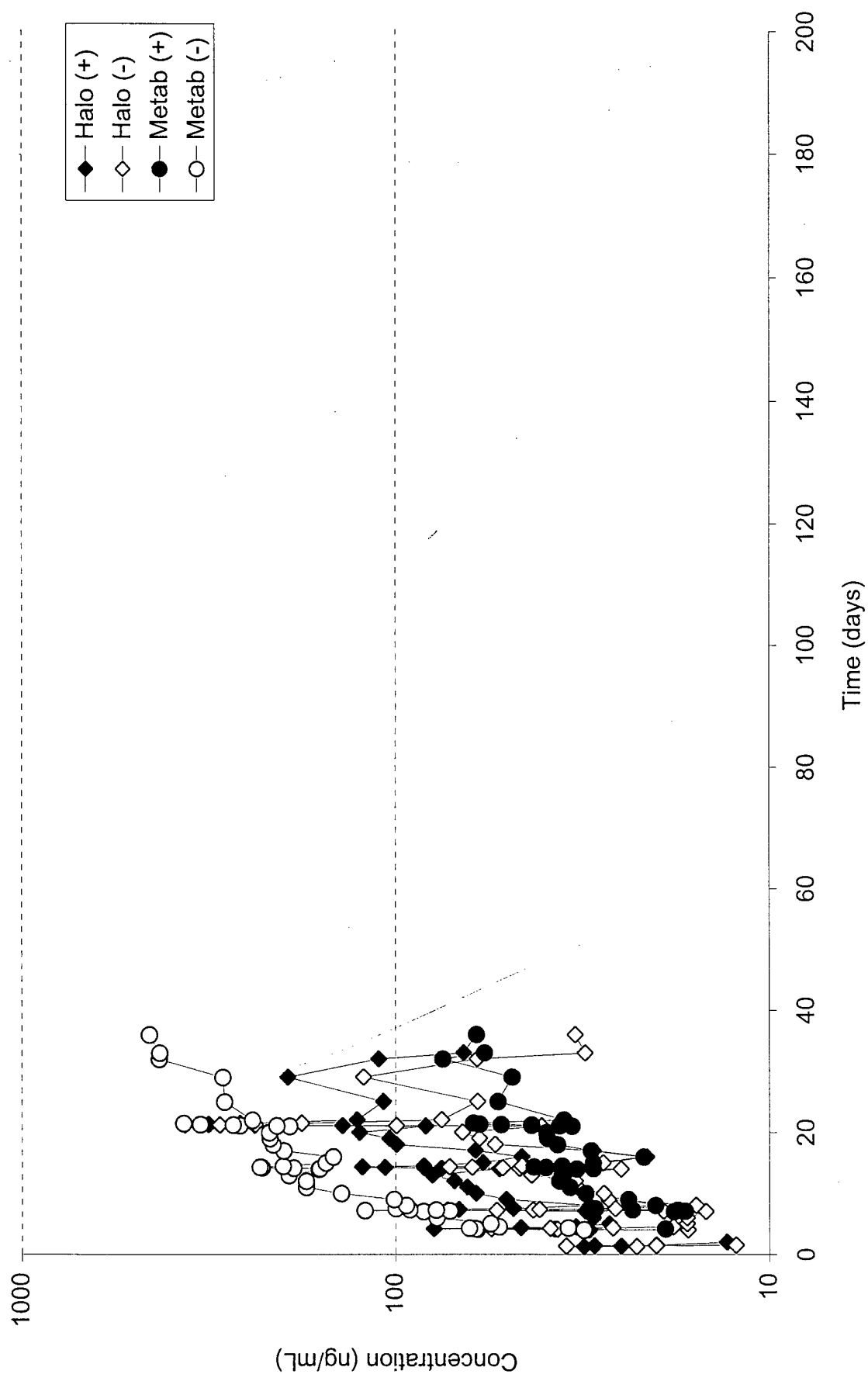


Figure 55c: Halofantrine and Metabolite Concentrations for Subject 04

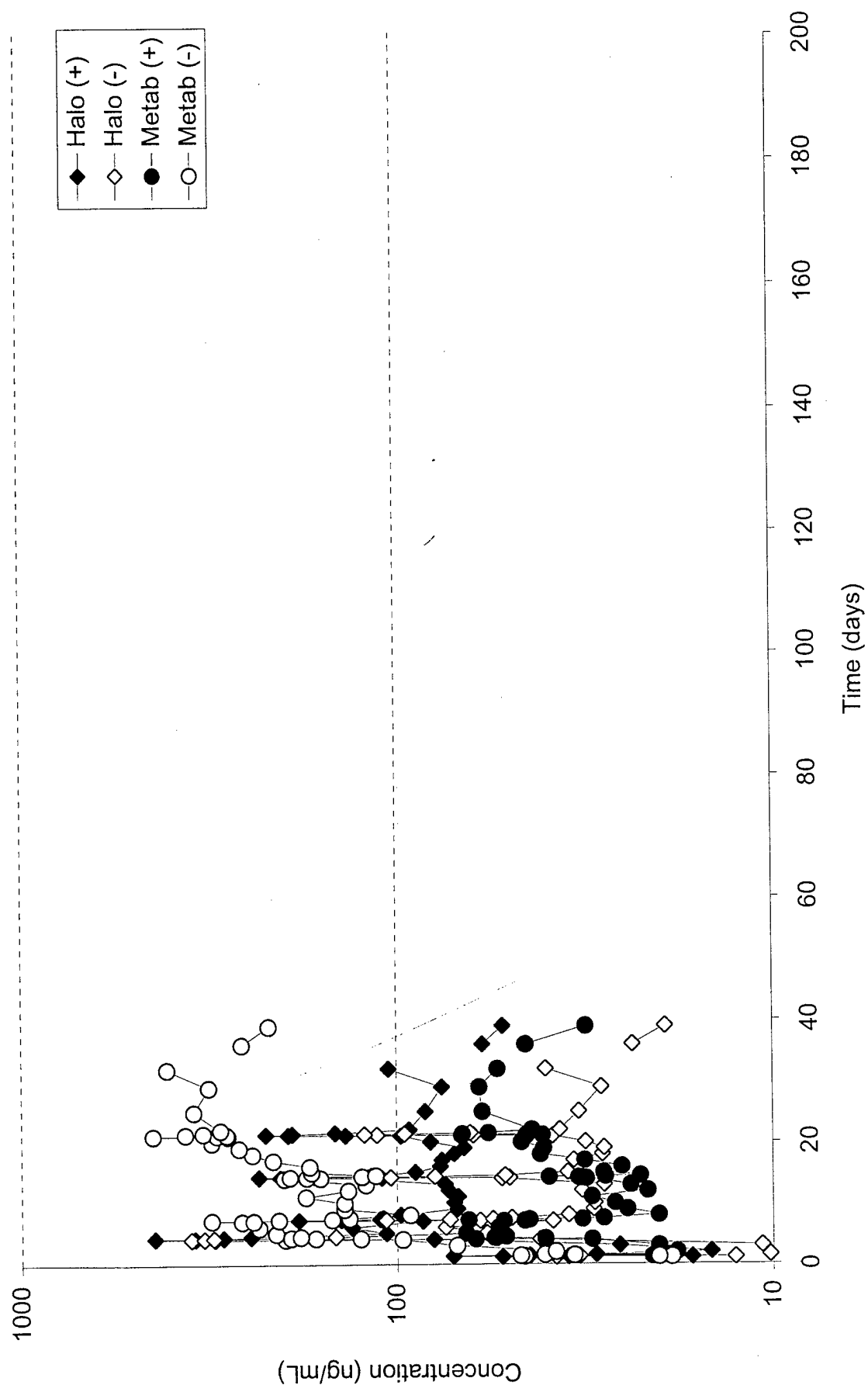


Figure 55d: Halofantrine and Metabolite Concentrations for Subject 05

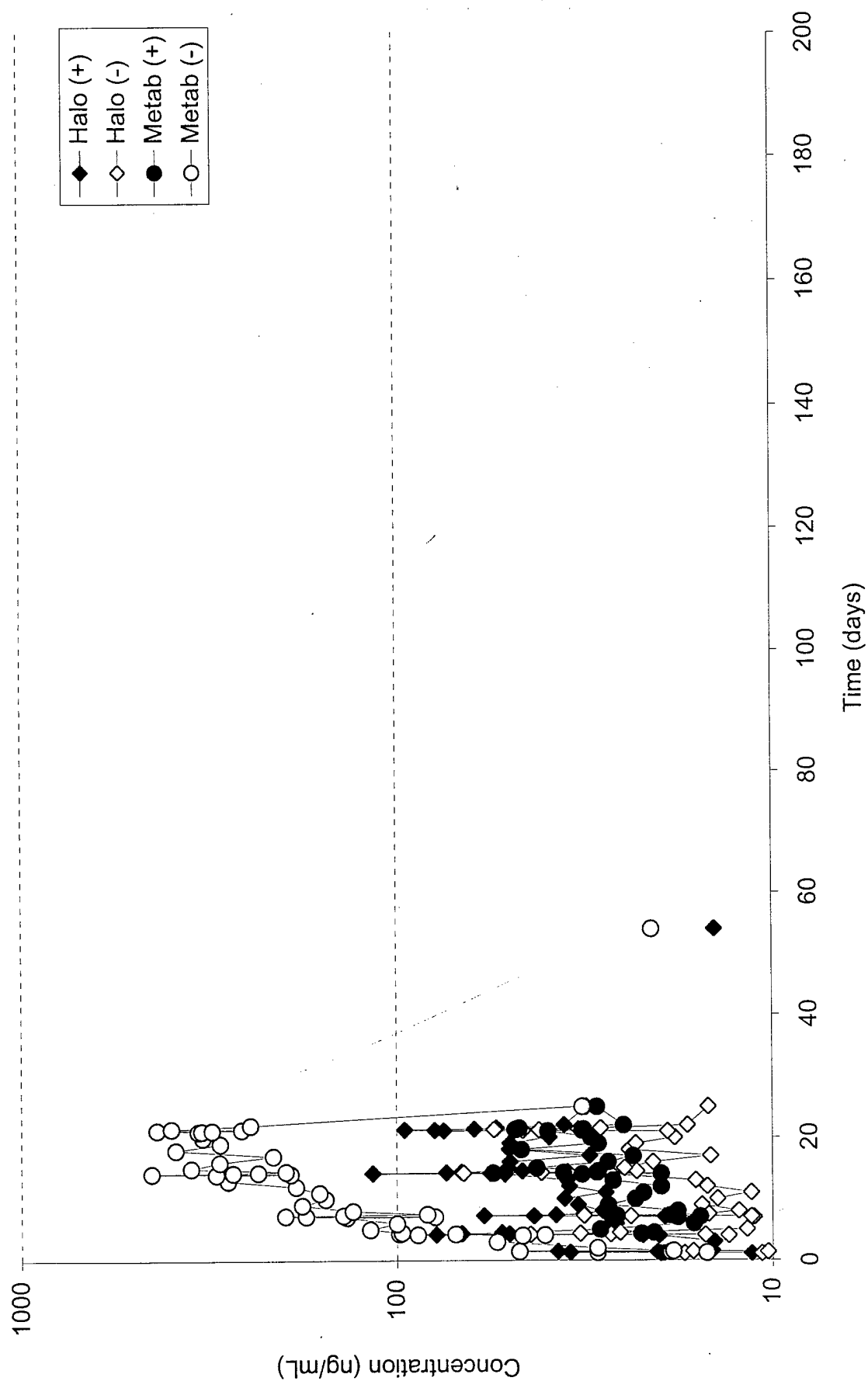


Figure 55e: Halofantrine and Metabolite Concentrations for Subject 07

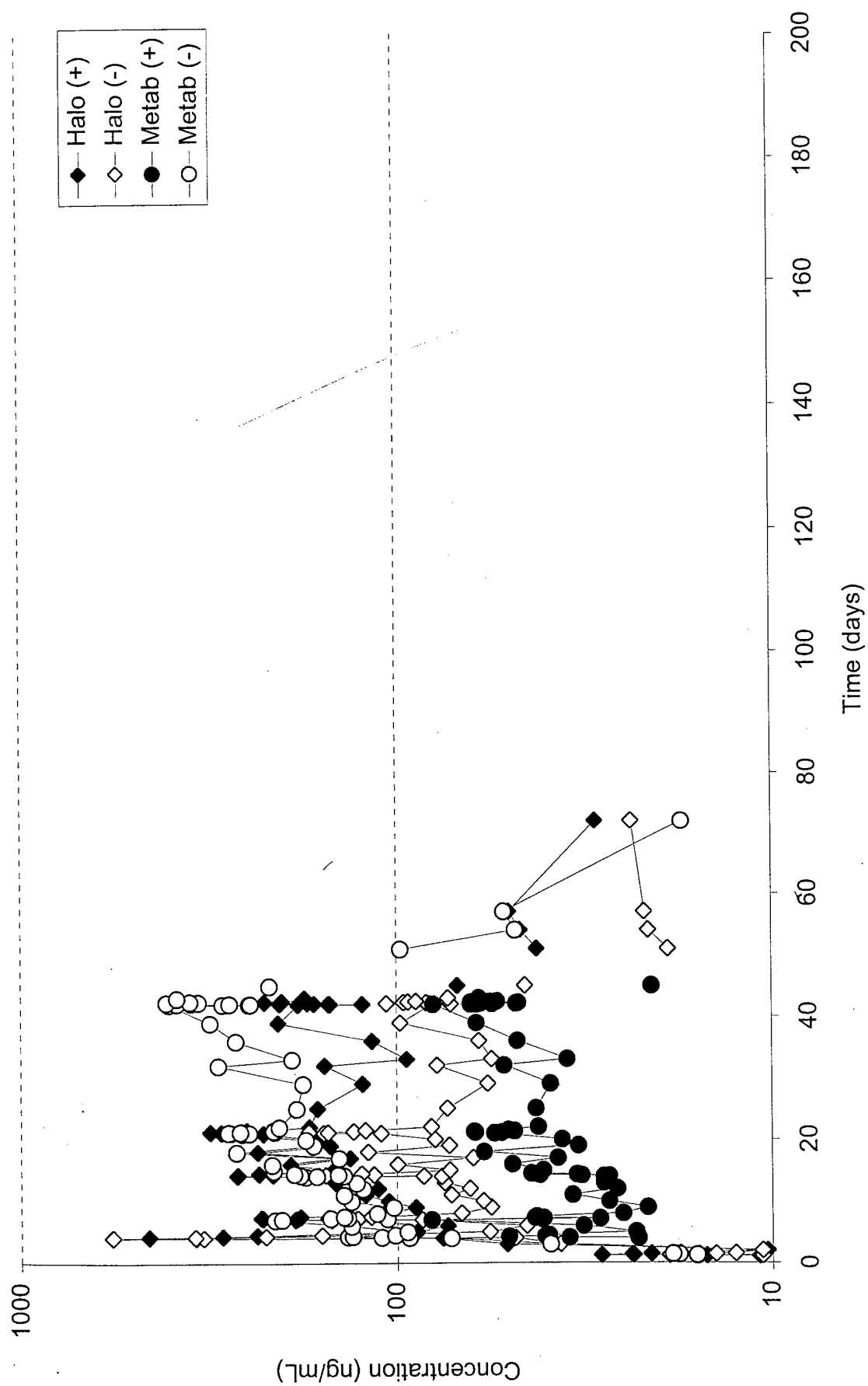


Figure 55f: Halofantrine and Metabolite Concentrations for Subject 08

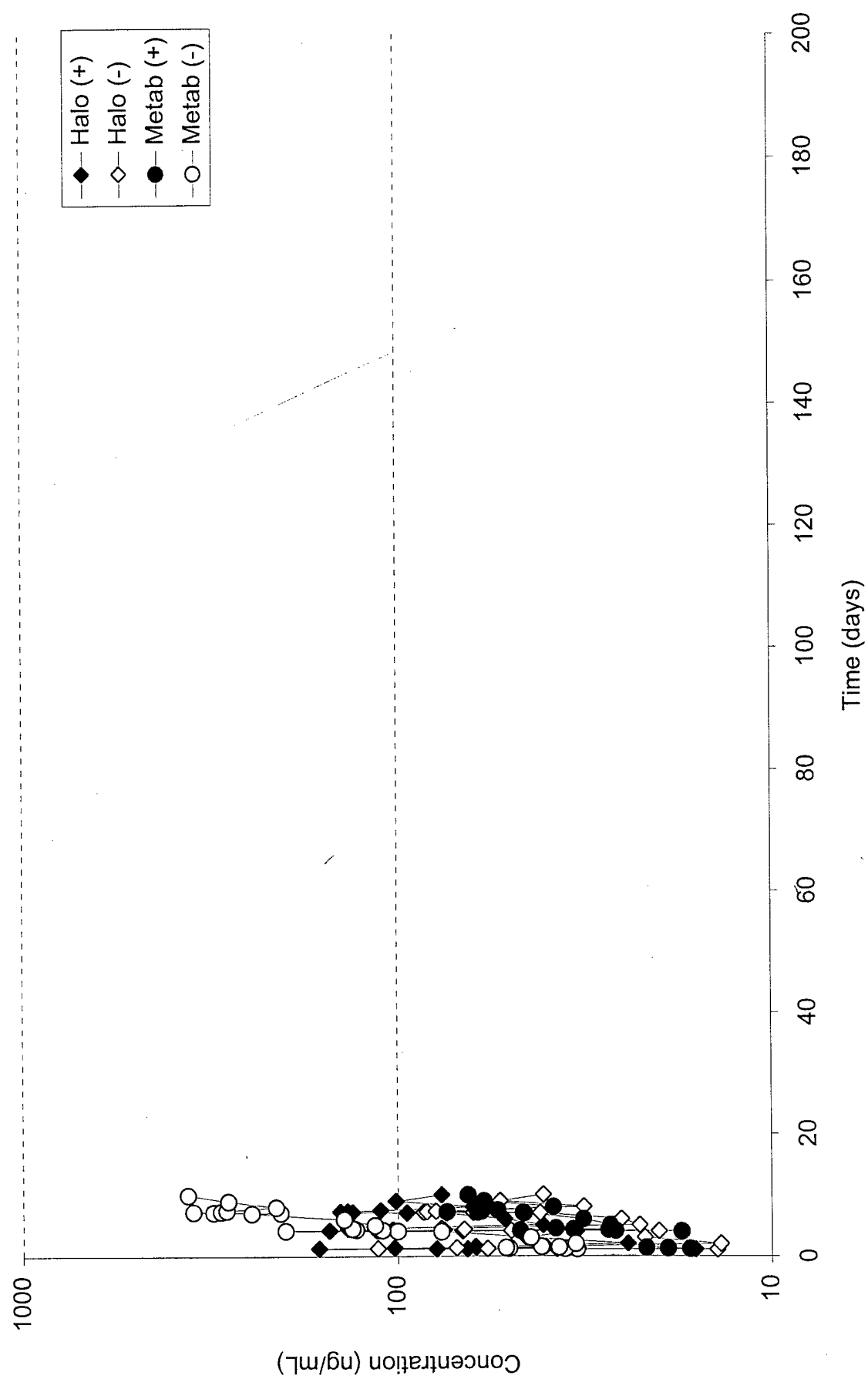


Figure 55g: Halofantrine and Metabolite Concentrations for Subject 09

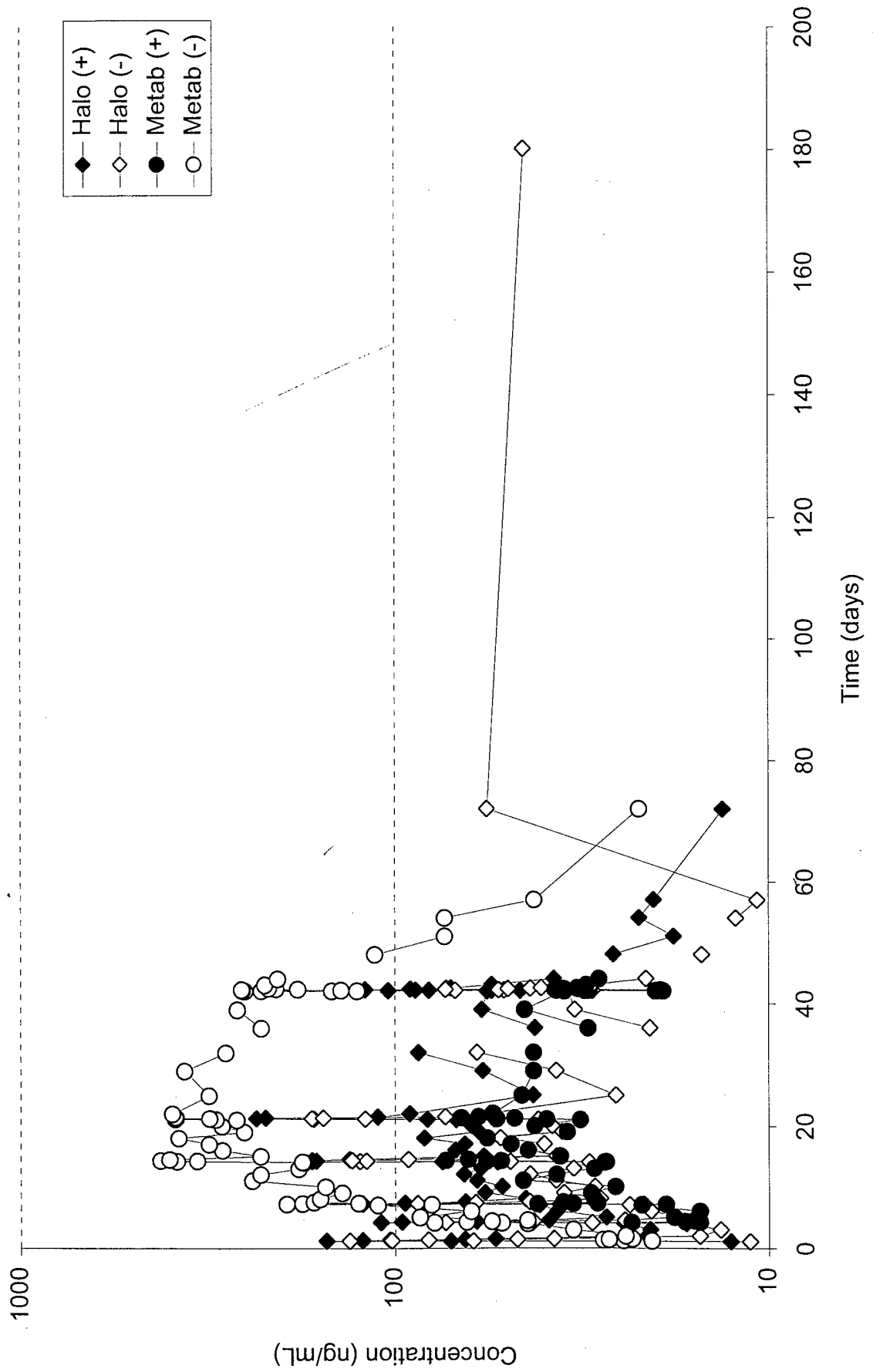


Figure 55h: Halofantrine and Metabolite Concentrations for Subject 10

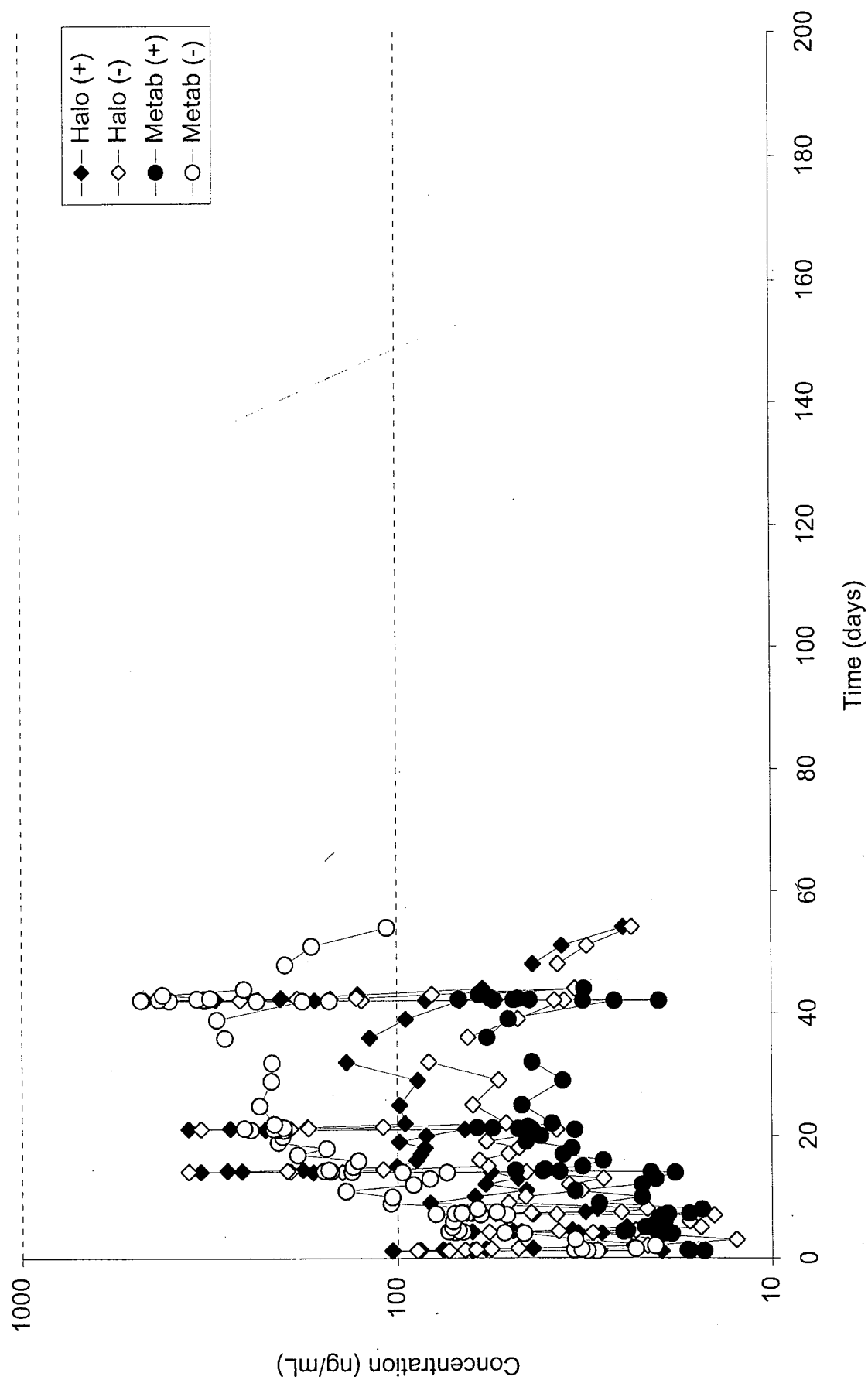


Figure 55I: Halofantrine and Metabolite Concentrations for Subject 11

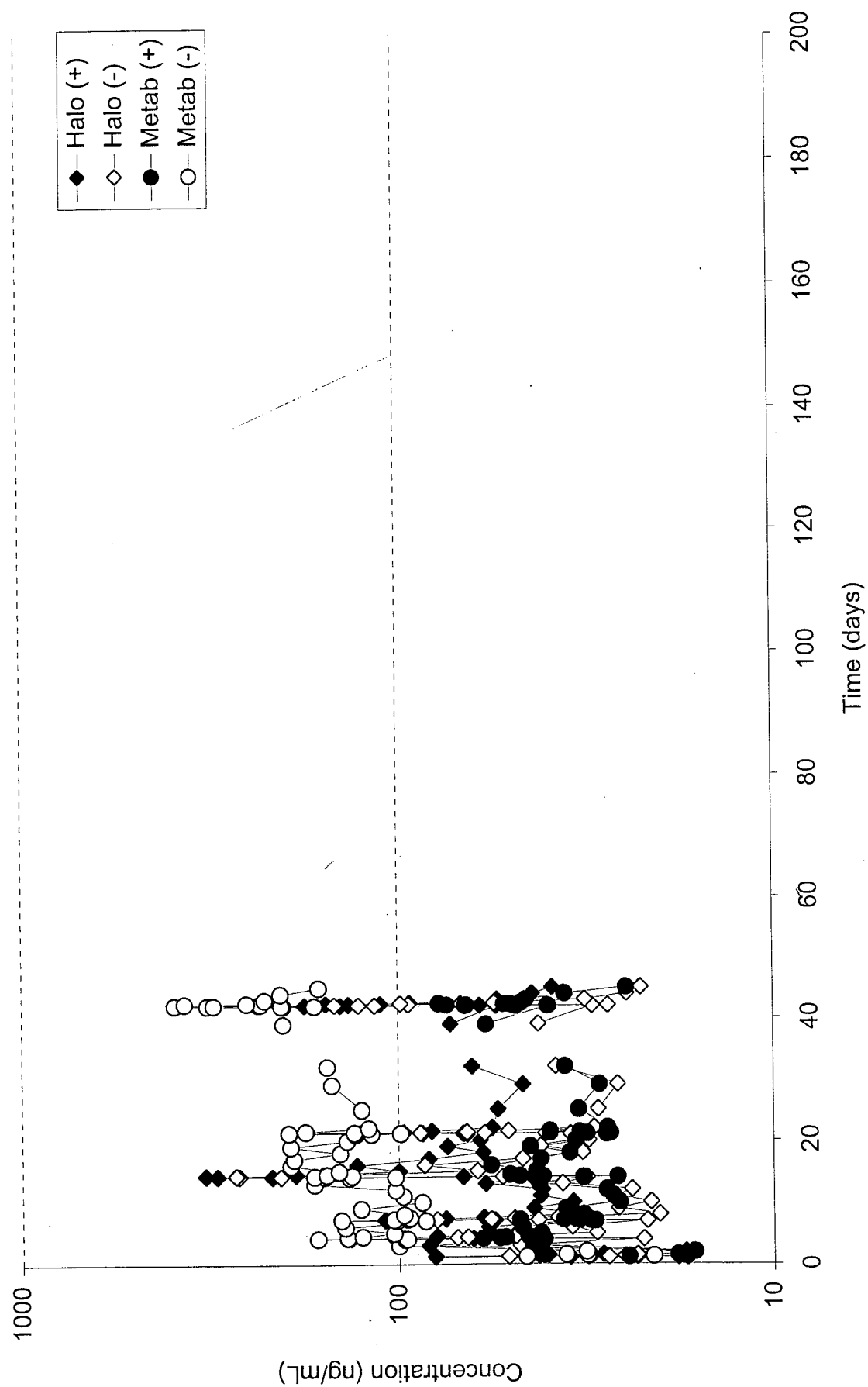


Figure 55j: Halofantrine and Metabolite Concentrations for Subject 14

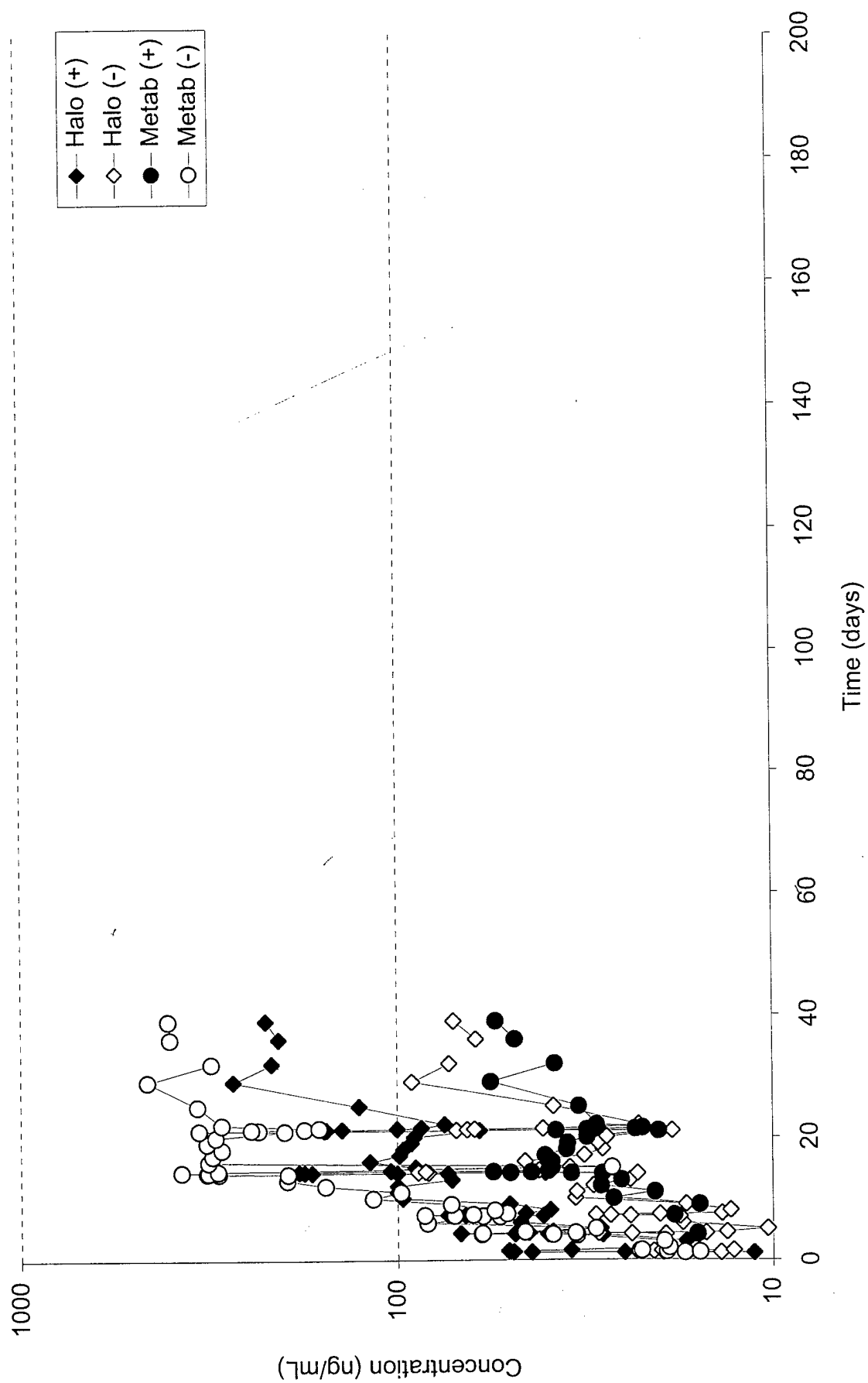


Figure 55k: Halofantrine and Metabolite Concentrations for Subject 15

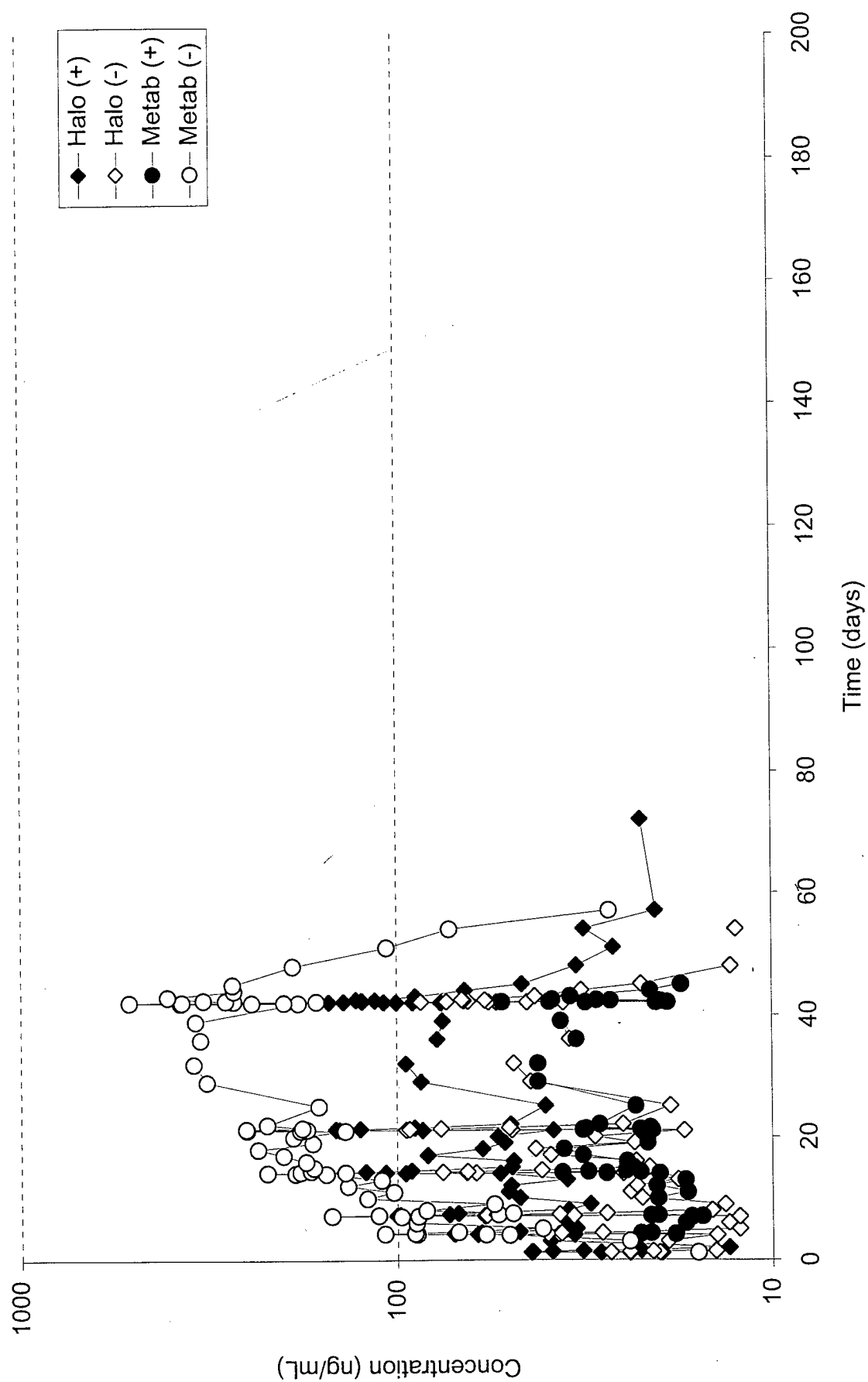


Figure 55L: Halofantrine and Metabolite Concentrations for Subject 16

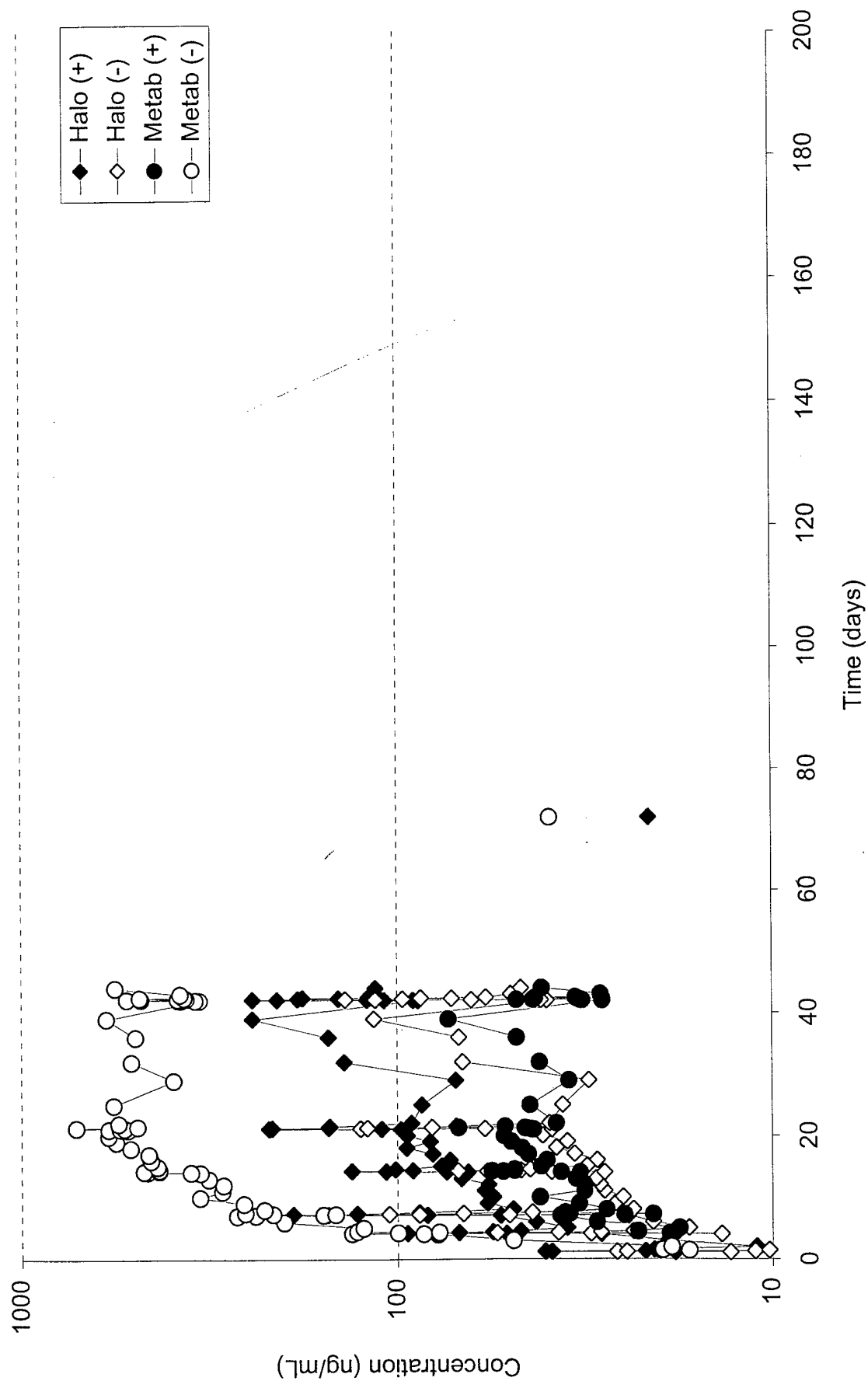


Figure 55m: Halofantrine and Metabolite Concentrations for Subject 18

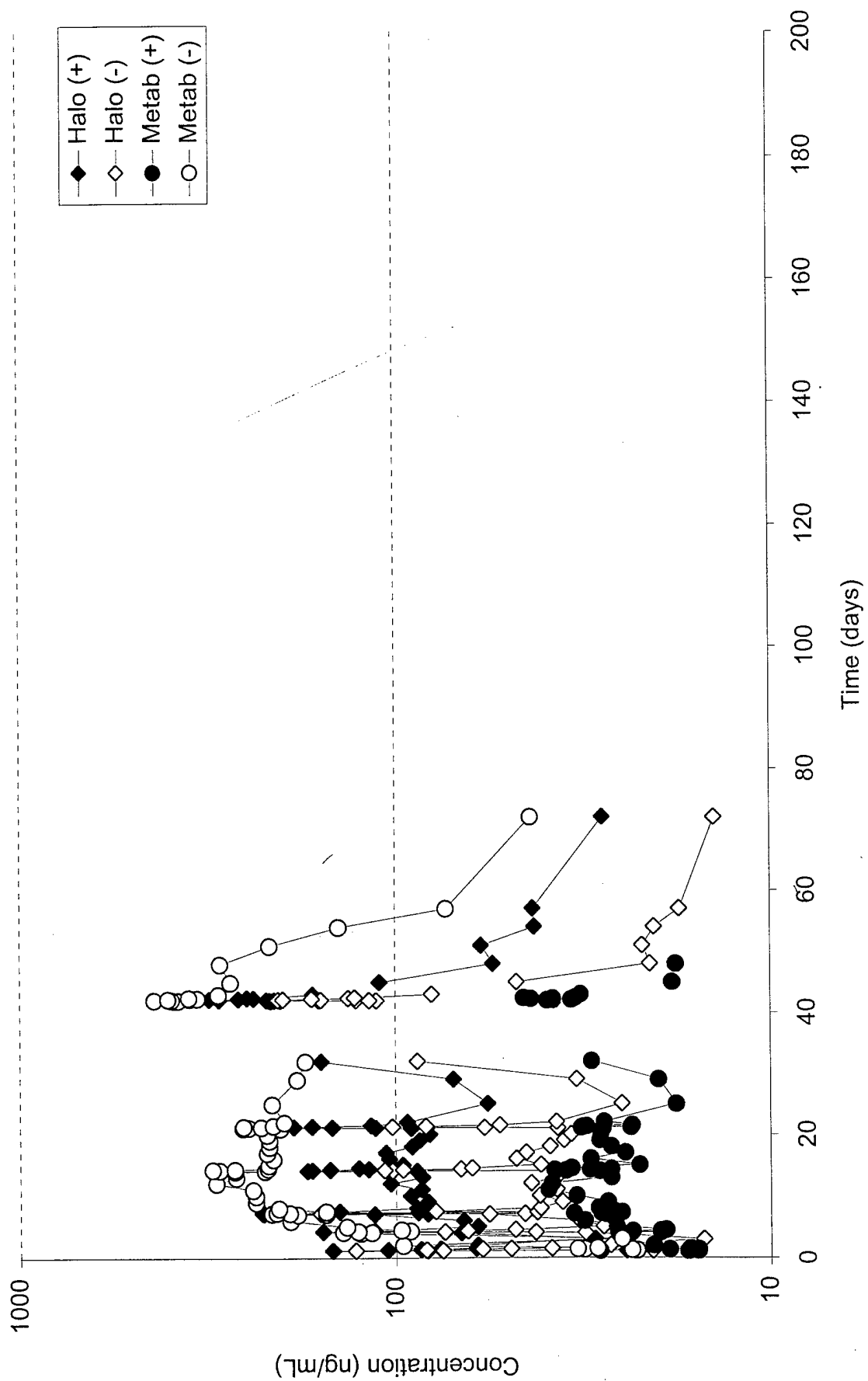


Figure 55n: Halofantrine and Metabolite Concentrations for Subject 19

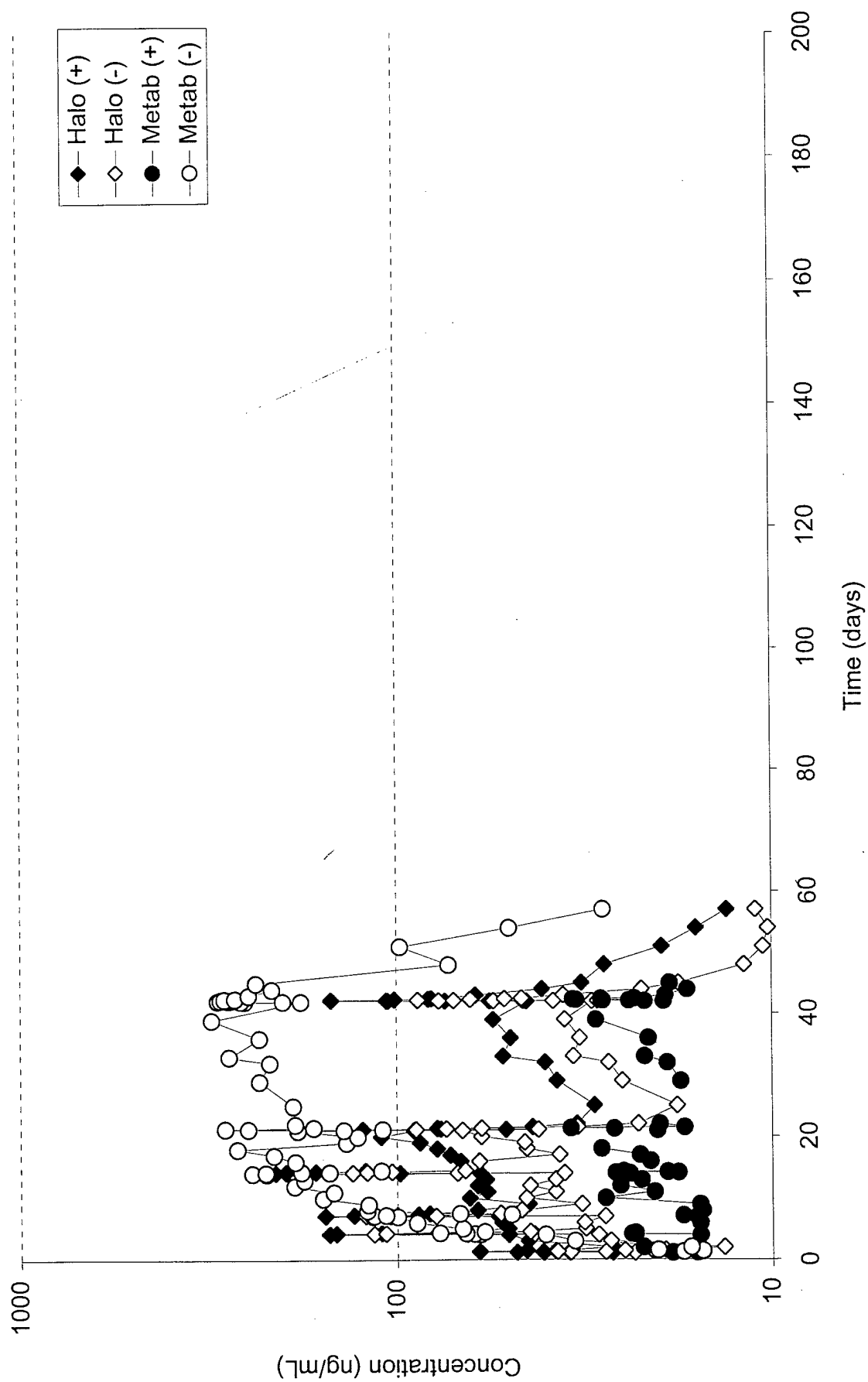


Figure 55o: Halofantrine and Metabolite Concentrations for Subject 20

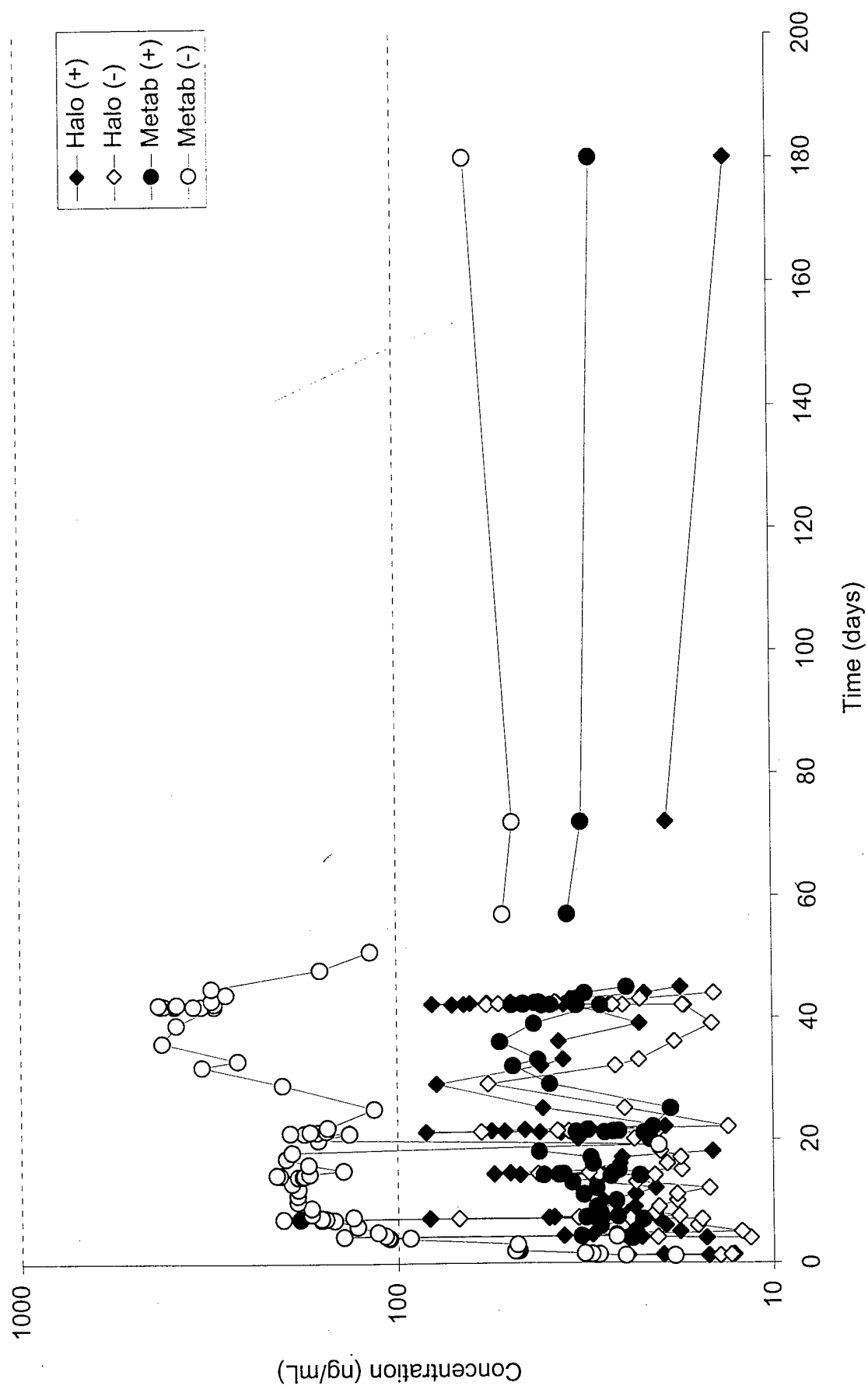
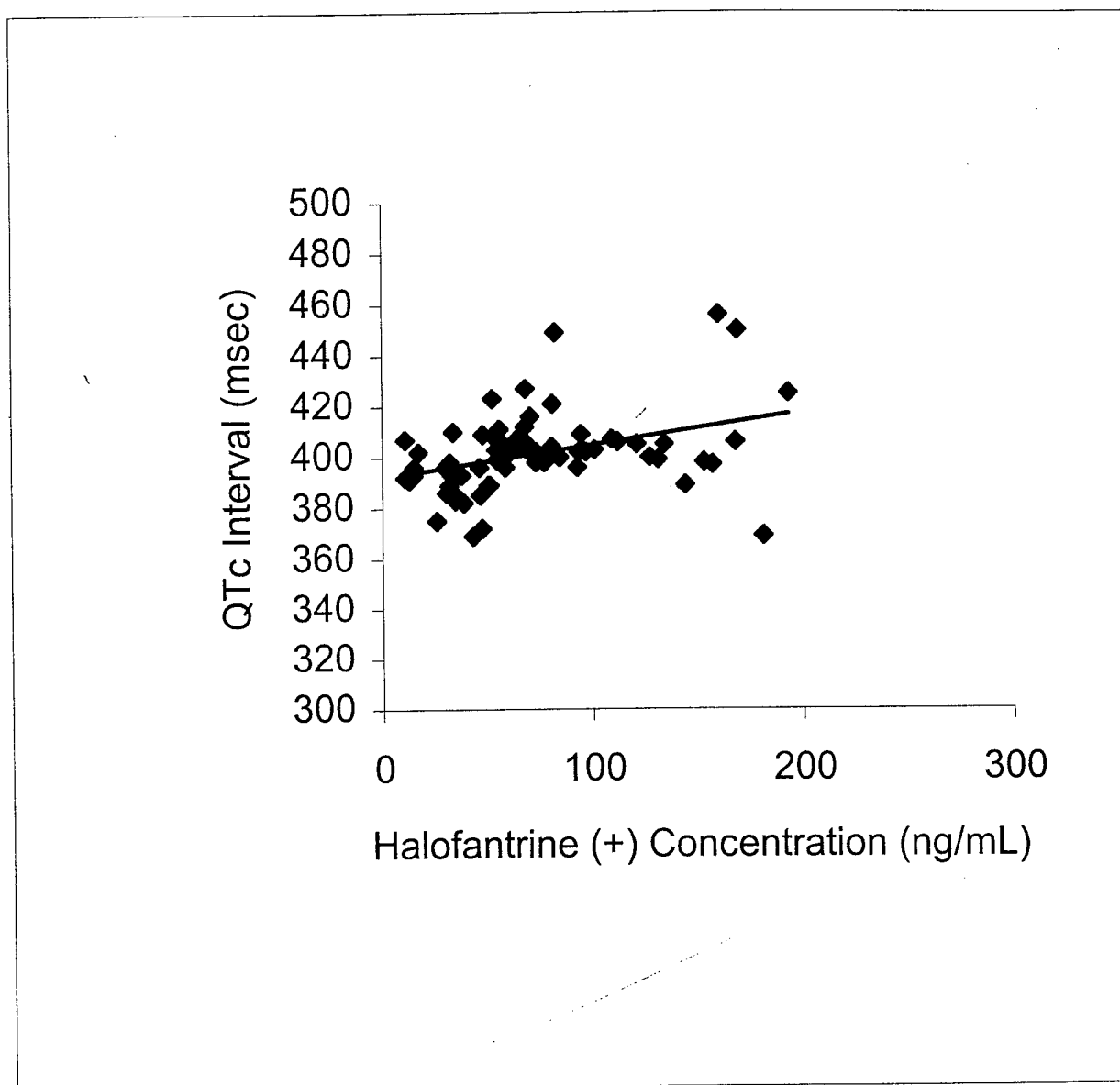


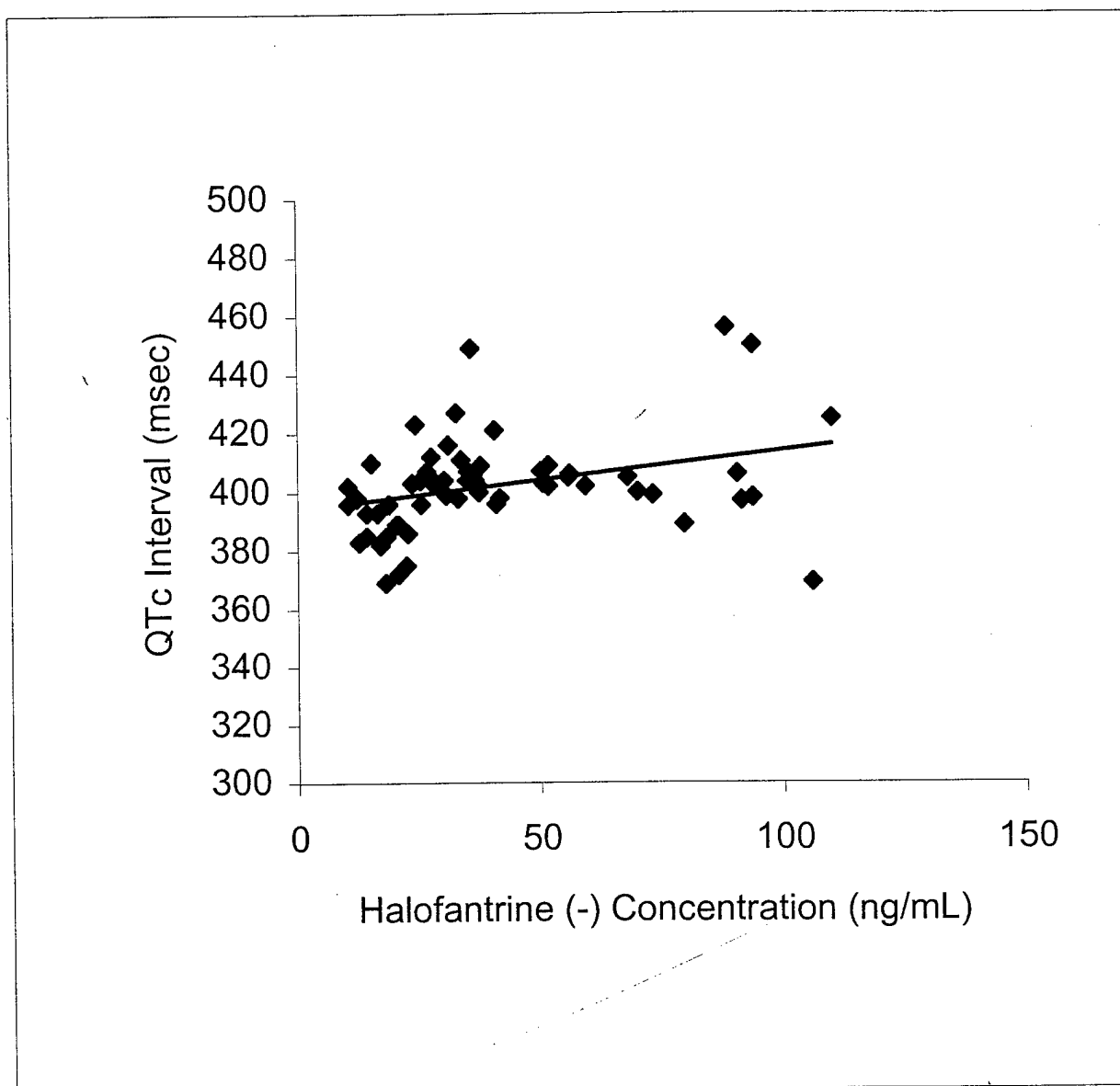
Figure 56a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 01



$$QTc = 392.1 + 0.1281 * Halo(+)$$

$$\text{Correlation Coefficient (r)} = 0.361$$

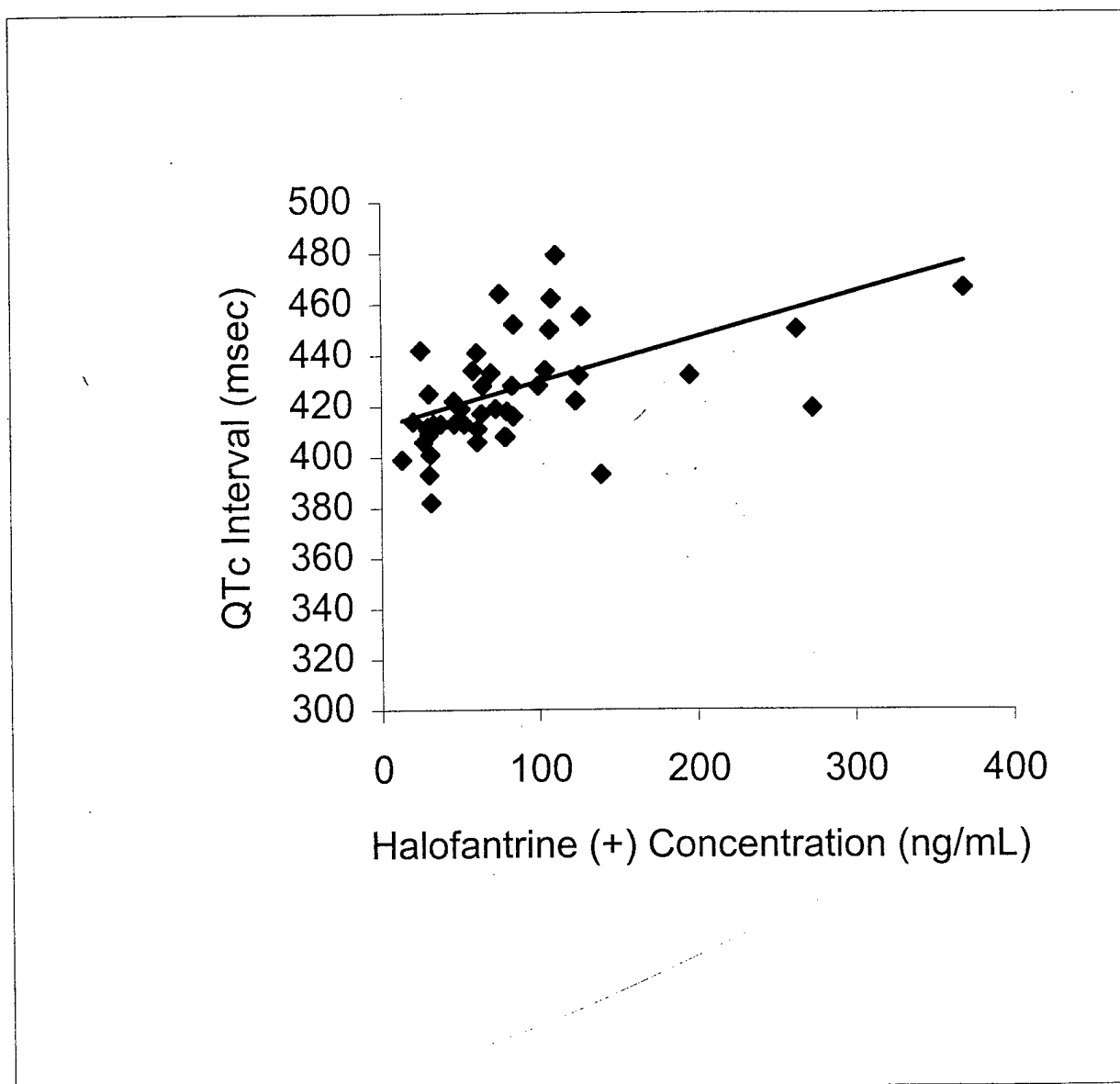
Figure 56b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 01



$$QTc = 394.2 + 0.1979 * \text{Halo}(-)$$

Correlation Coefficient (r) = 0.308

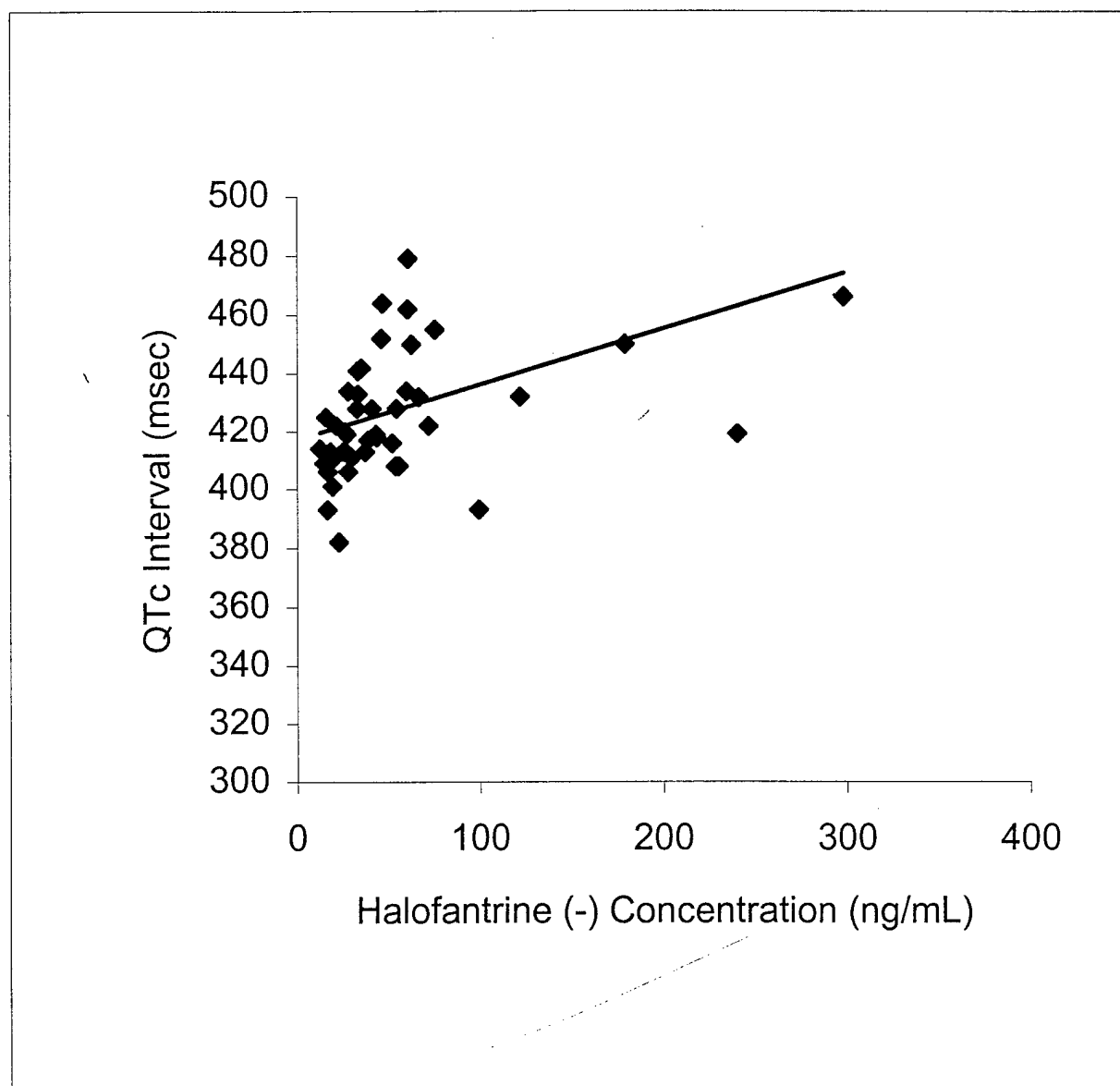
Figure 57a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 02



$$QTc = 412.2 + 0.1748 * Halo(+)$$

Correlation Coefficient (r) = 0.511

Figure 57b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 02



$$QTc = 417.2 + 0.1904 * Halo(-)$$

Correlation Coefficient (r) = 0.447

Figure 58a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 04

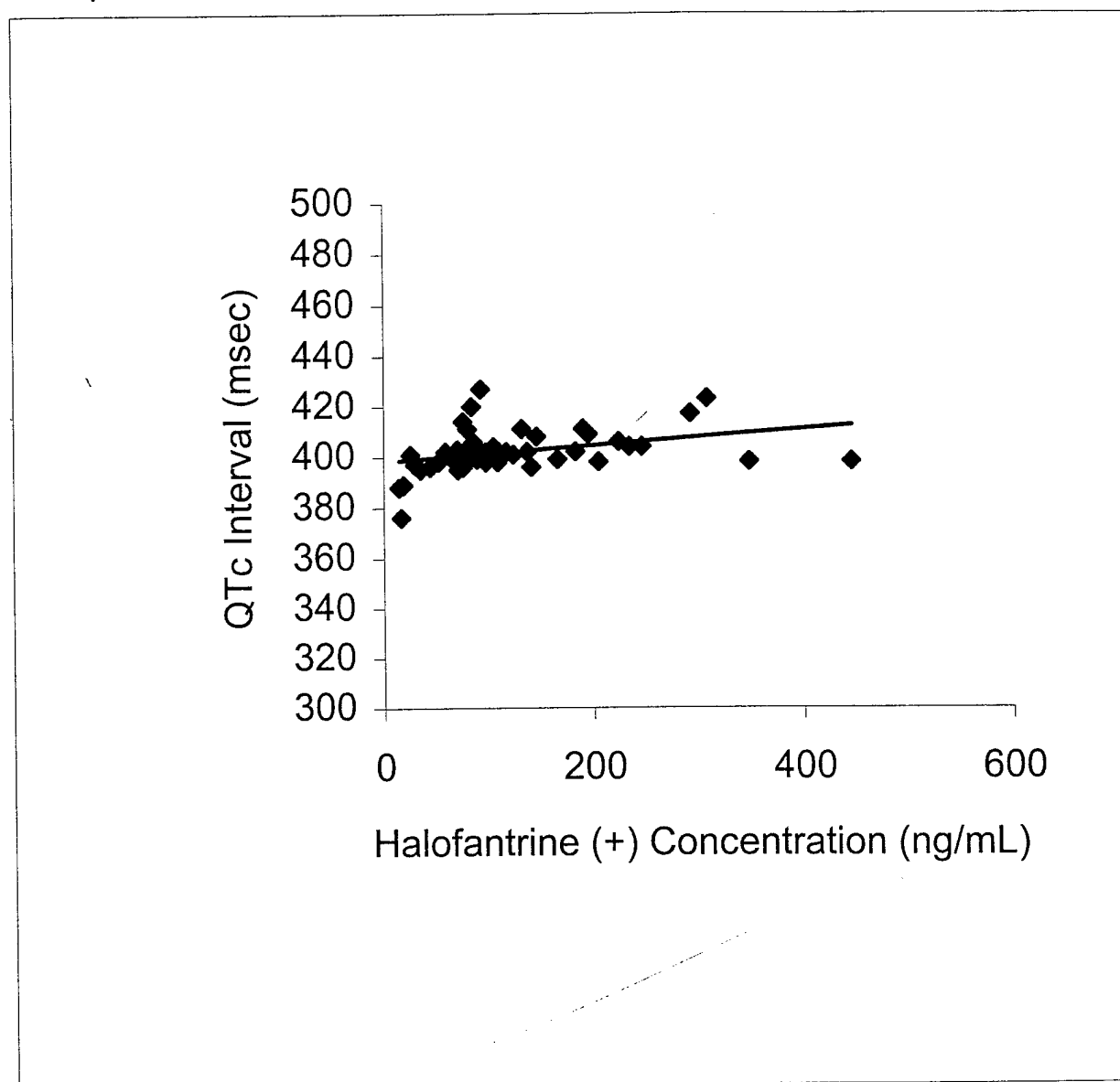
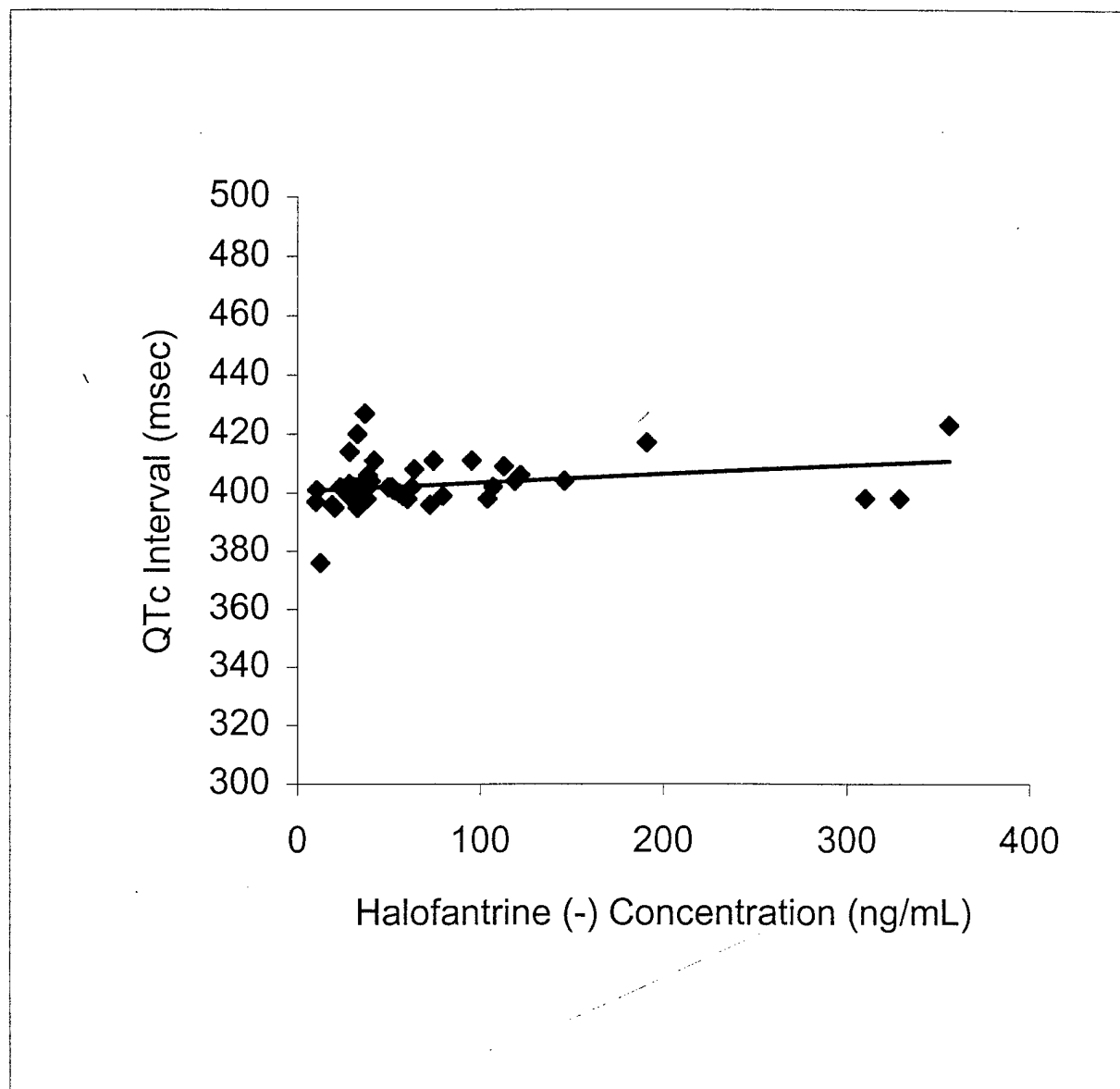


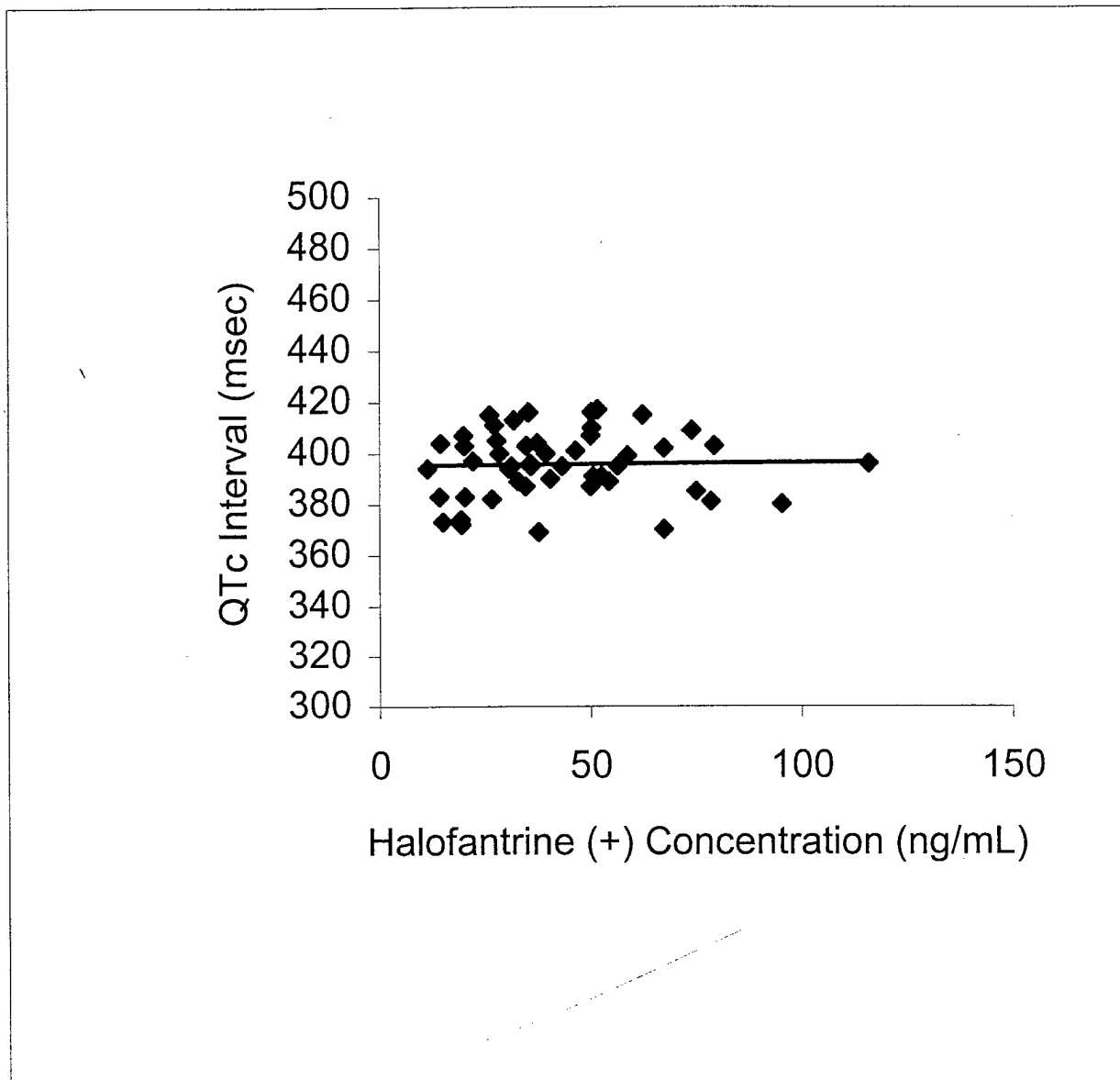
Figure 58b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 04



$$QTc = 400.6 + 0.0287 * Halo(-)$$

$$\text{Correlation Coefficient } (r) = 0.272$$

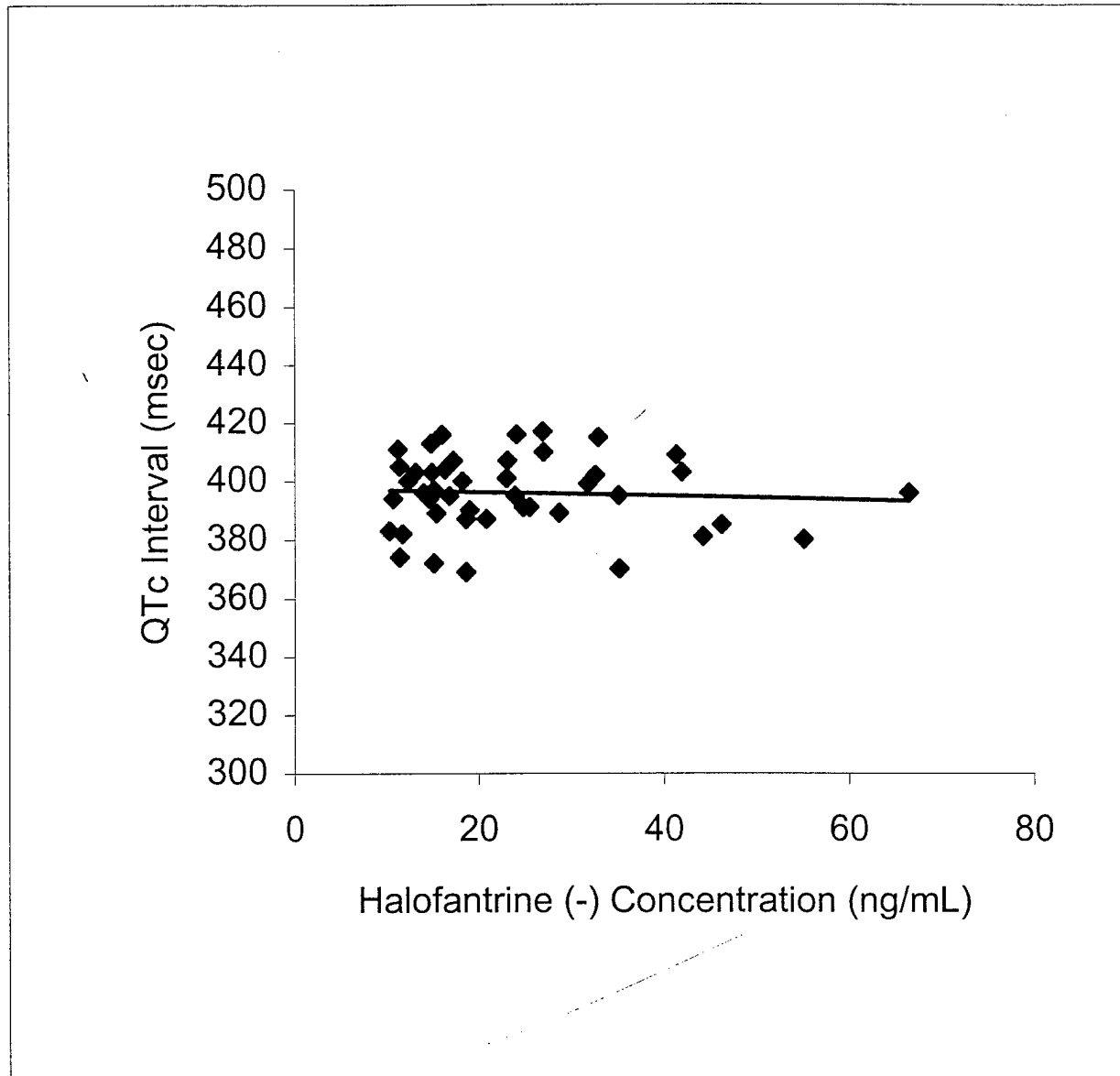
Figure 59a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 05



$$QTc = 395.3 + 0.0119 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.021$$

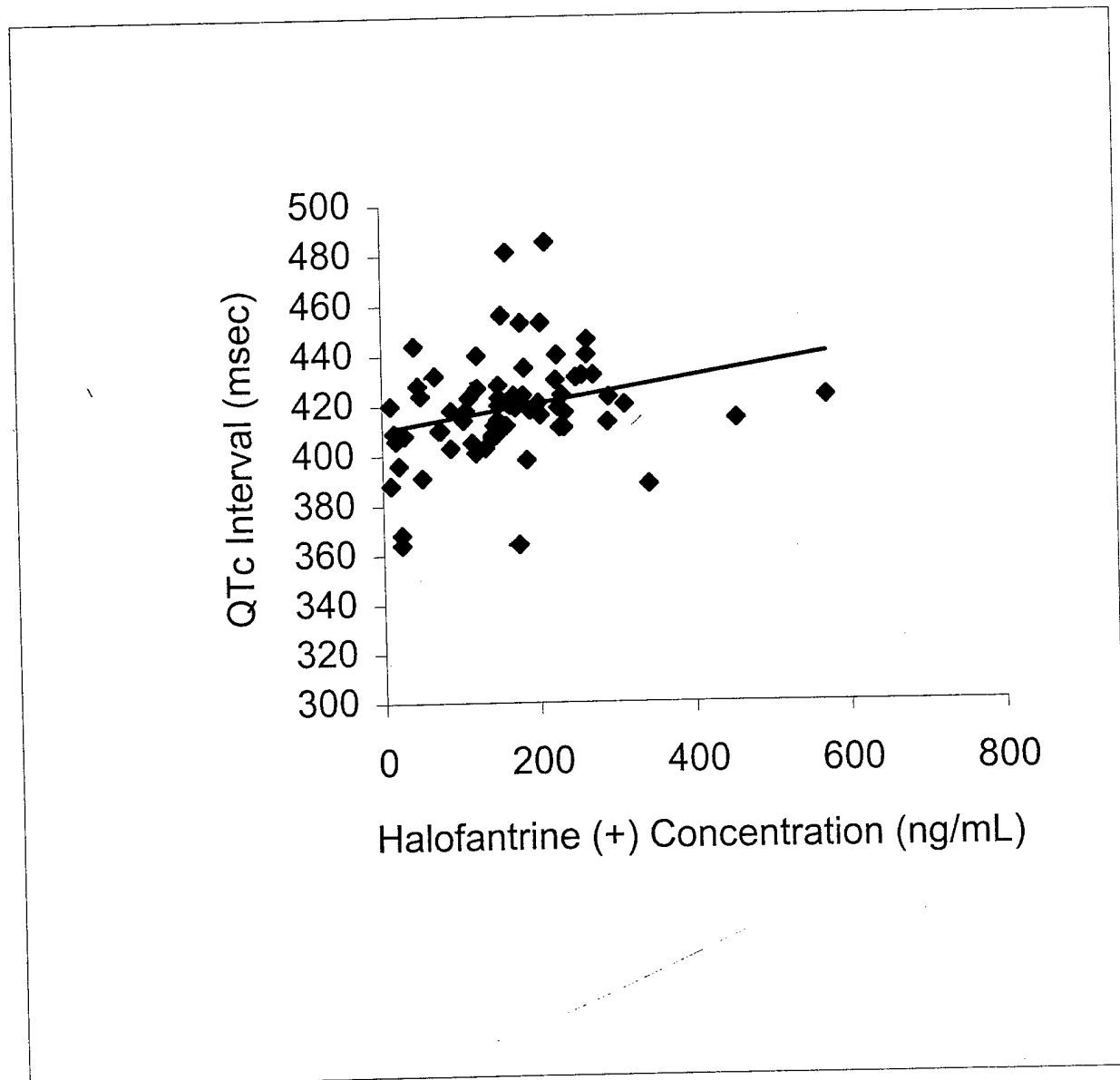
Figure 59b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 05



$$QTc = 397.5 + -0.0663 * \text{Halo}(-)$$

Correlation Coefficient (r) = -0.067

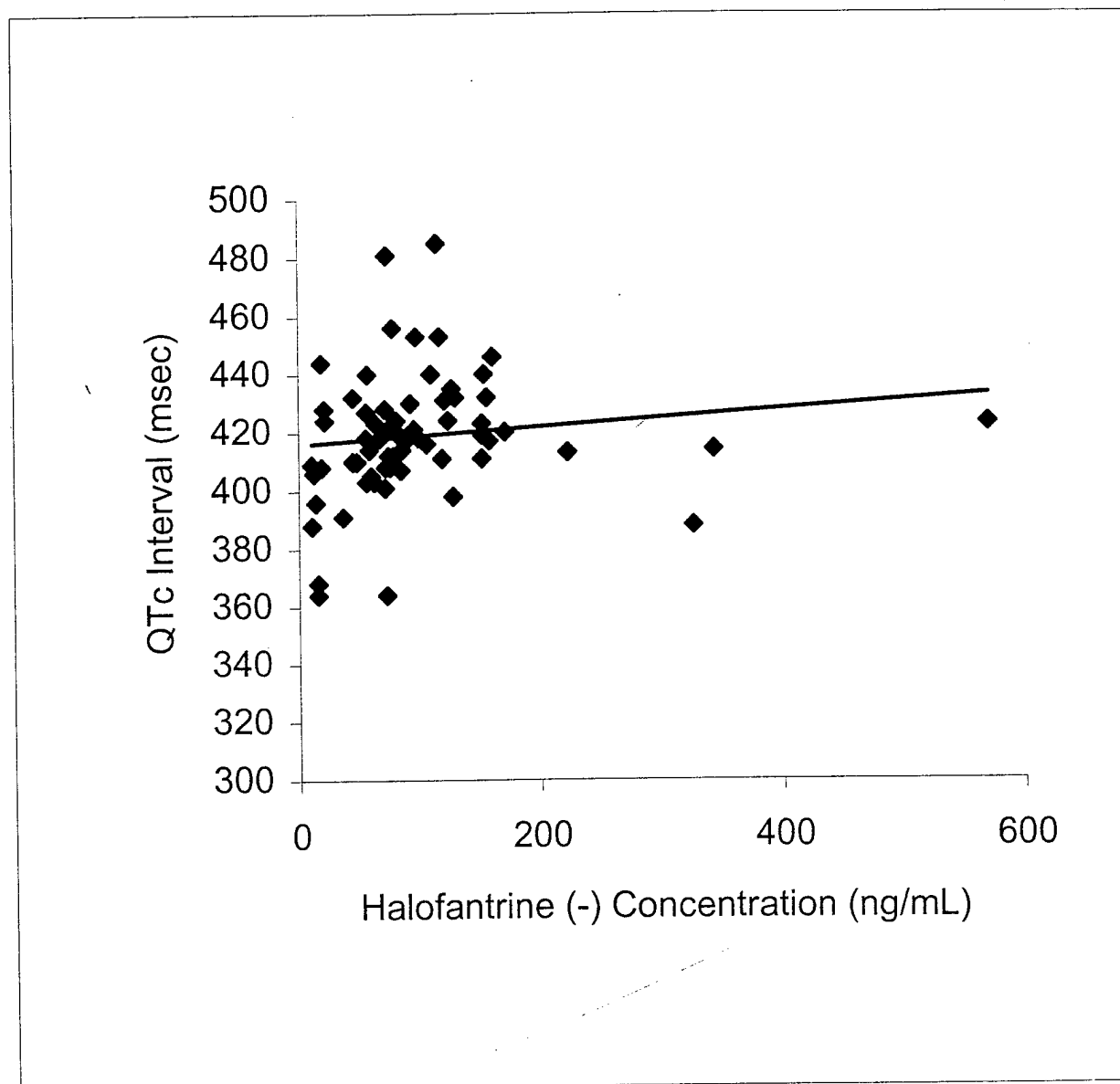
Figure 60a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 07



$$QTc = 410.1 + 0.0531 * \text{Halo}(+)$$

$$\text{Correlation Coefficient } (r) = 0.255$$

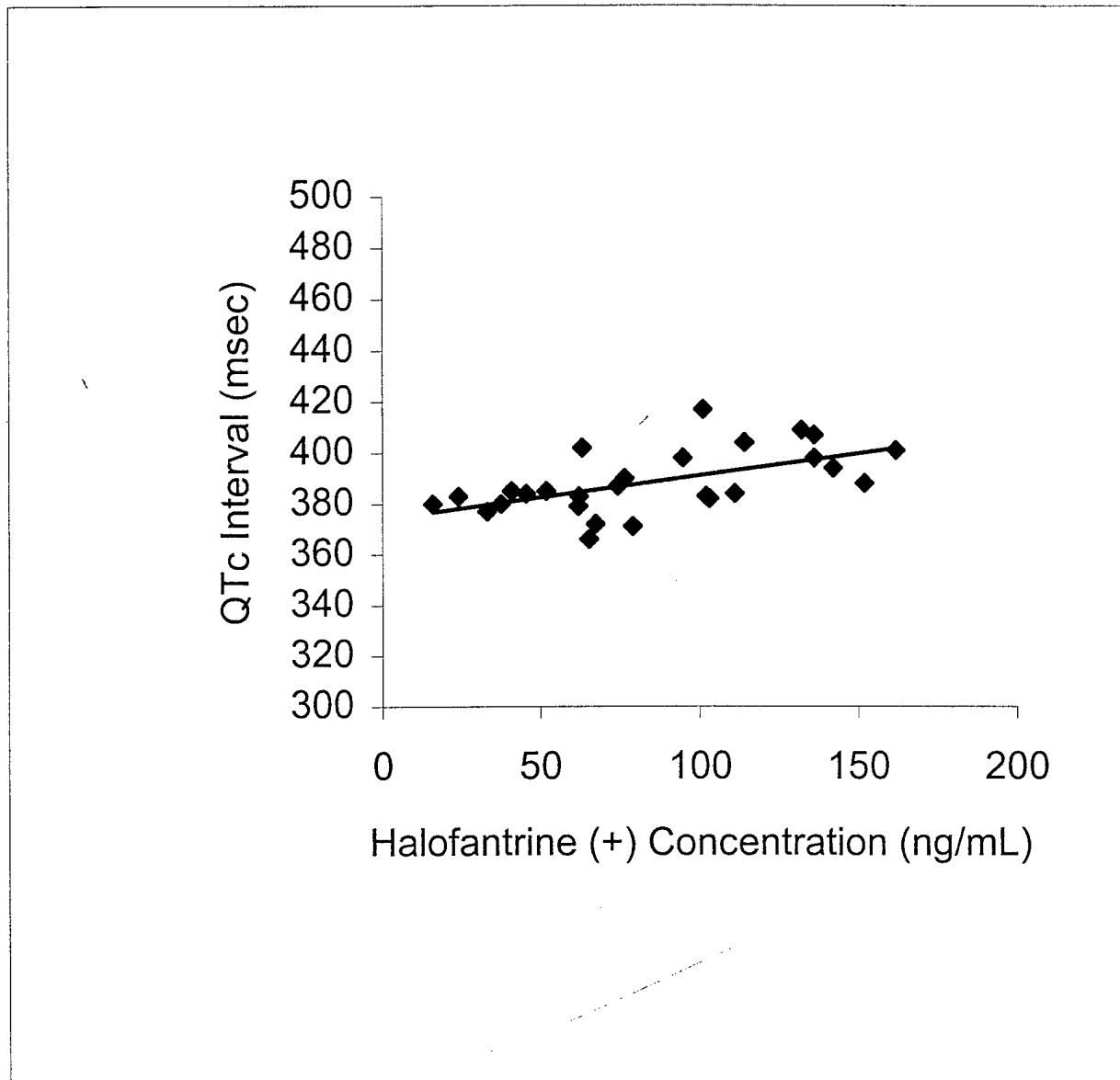
Figure 60b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 07



$$QTc = 415.8 + 0.0301 * Halo(-)$$

Correlation Coefficient (r) = 0.120

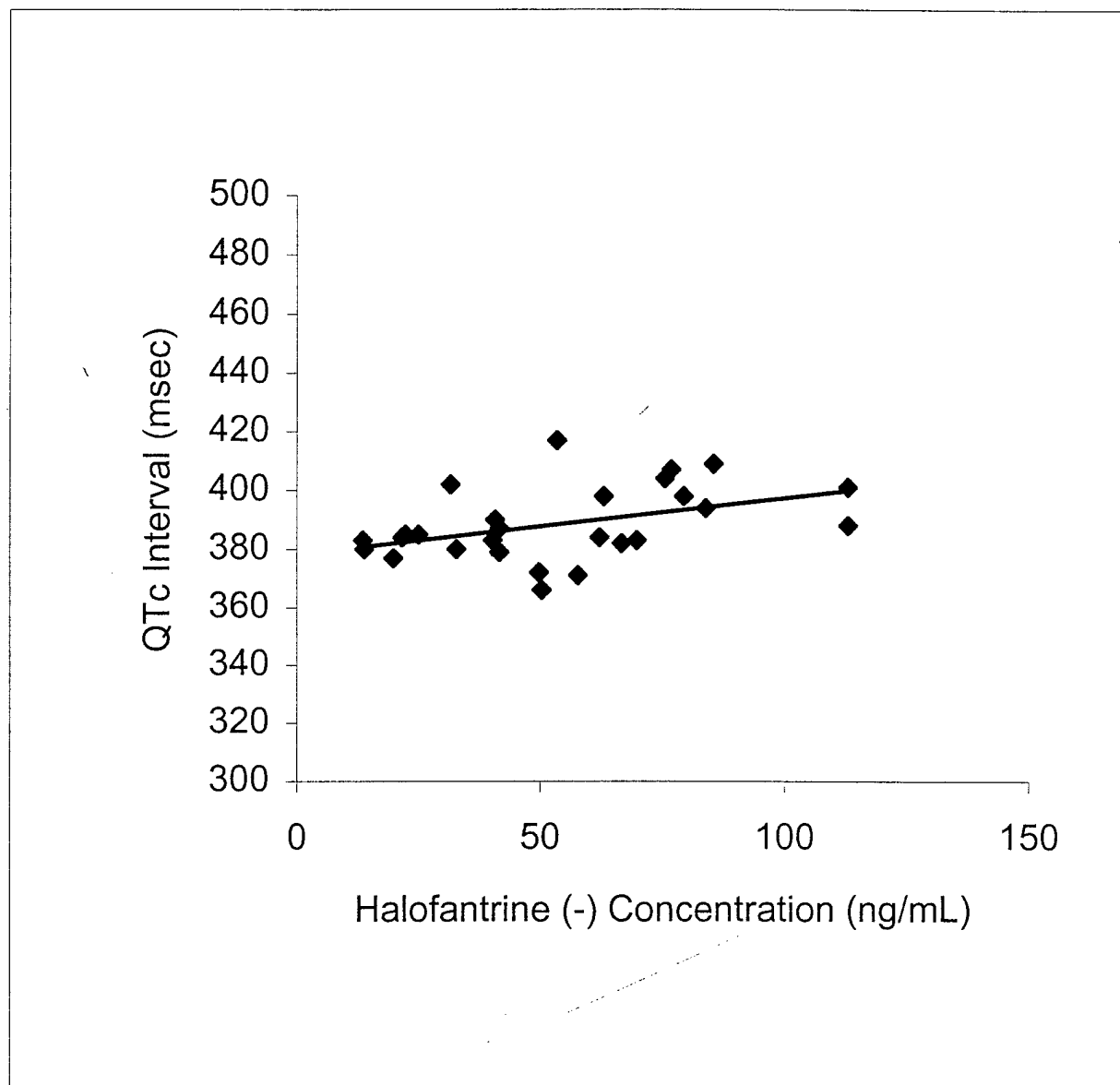
Figure 61a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 08



$$QTc = 373.9 + 0.1718 * Halo(+)$$

Correlation Coefficient (r) = 0.569

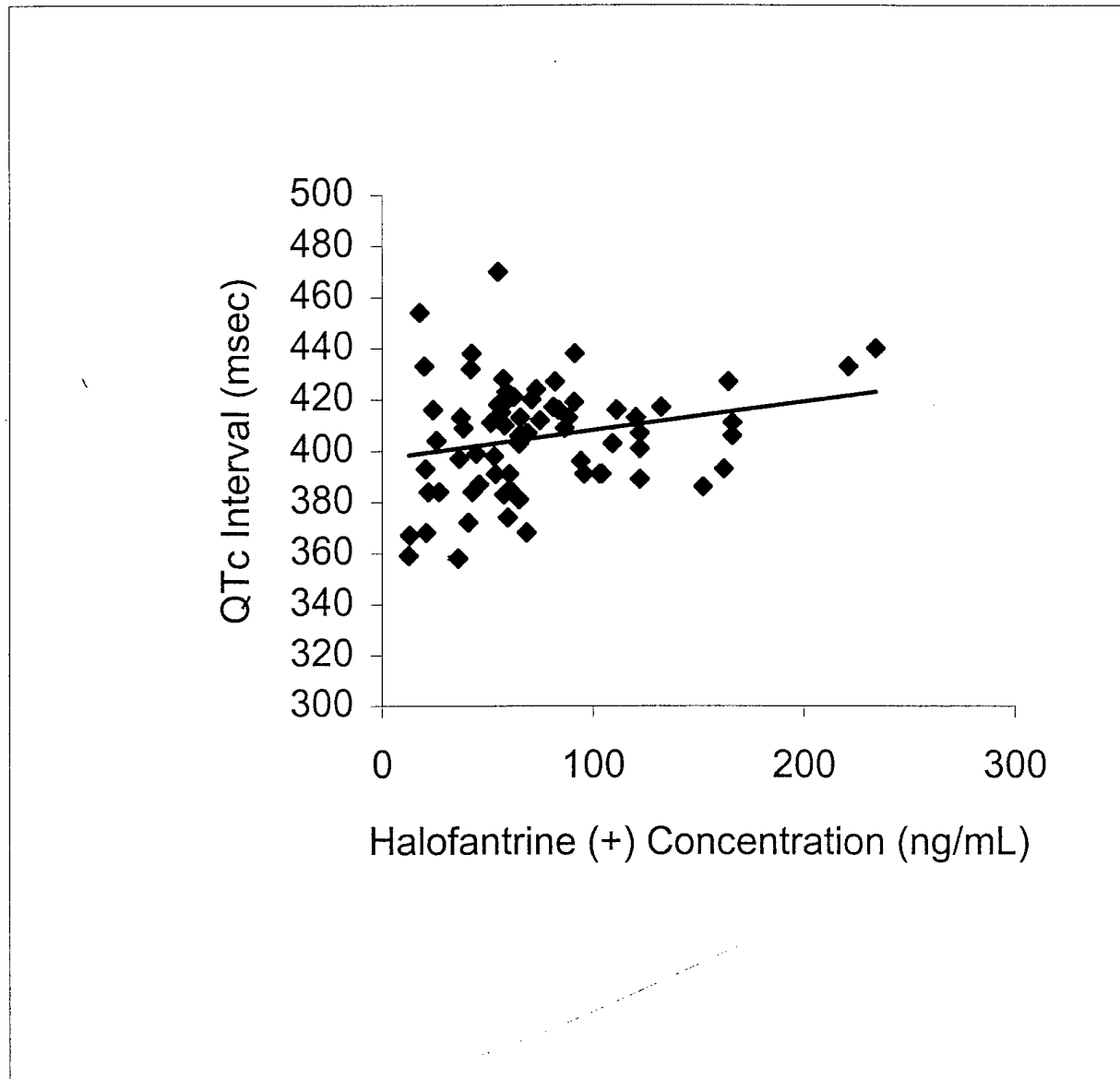
Figure 61b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 08



$$QTc = 378.2 + 0.1927 * Halo(-)$$

Correlation Coefficient (r) = 0.429

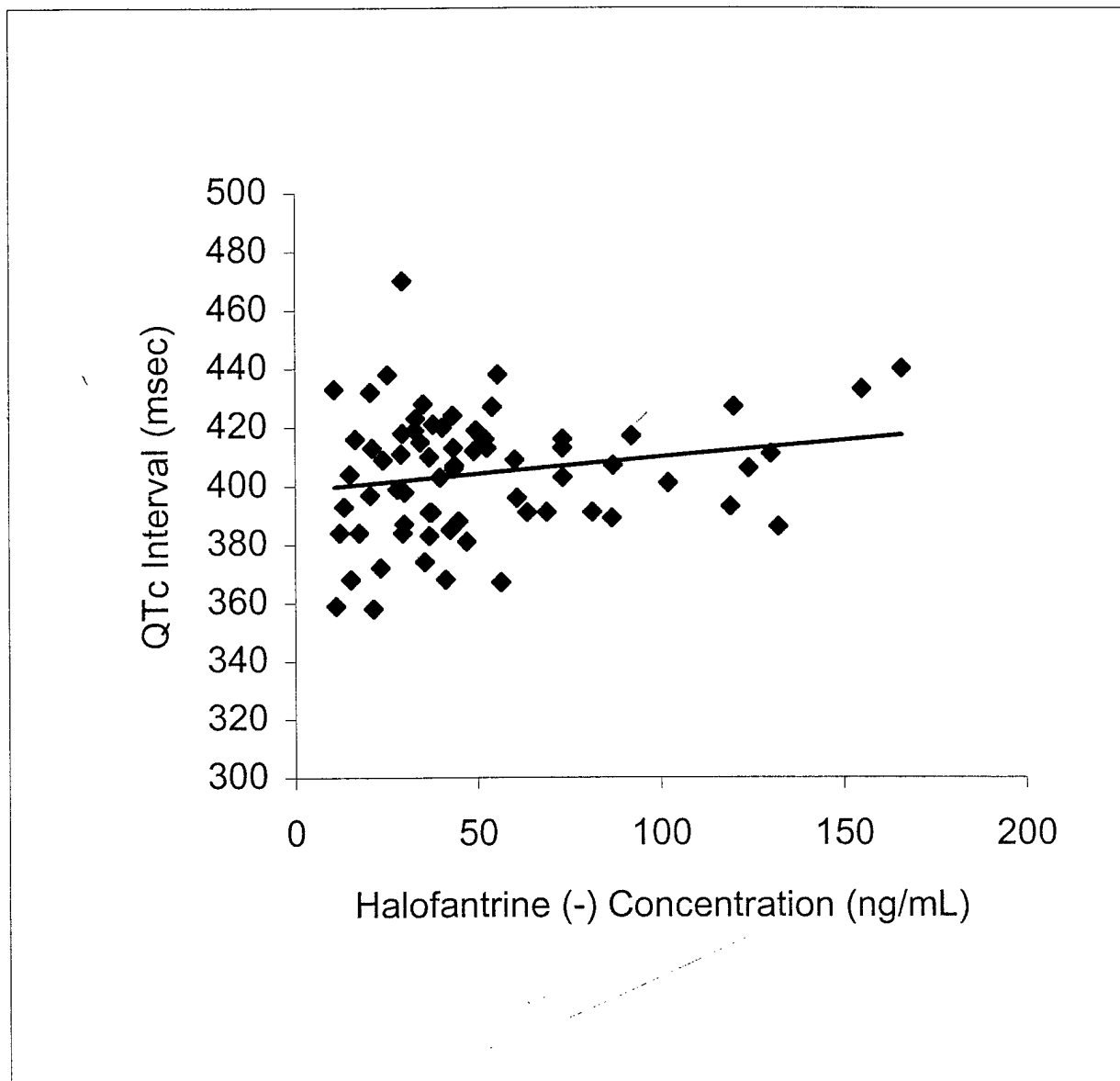
Figure 62a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 09



$$QTc = 397.1 + 0.1109 * Halo(+)$$

Correlation Coefficient (r) = 0.238

Figure 62b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 09



$$QTc = 398.6 + 0.1130 * \text{Halo}(-)$$

Correlation Coefficient (r) = 0.189

Figure 63a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 10

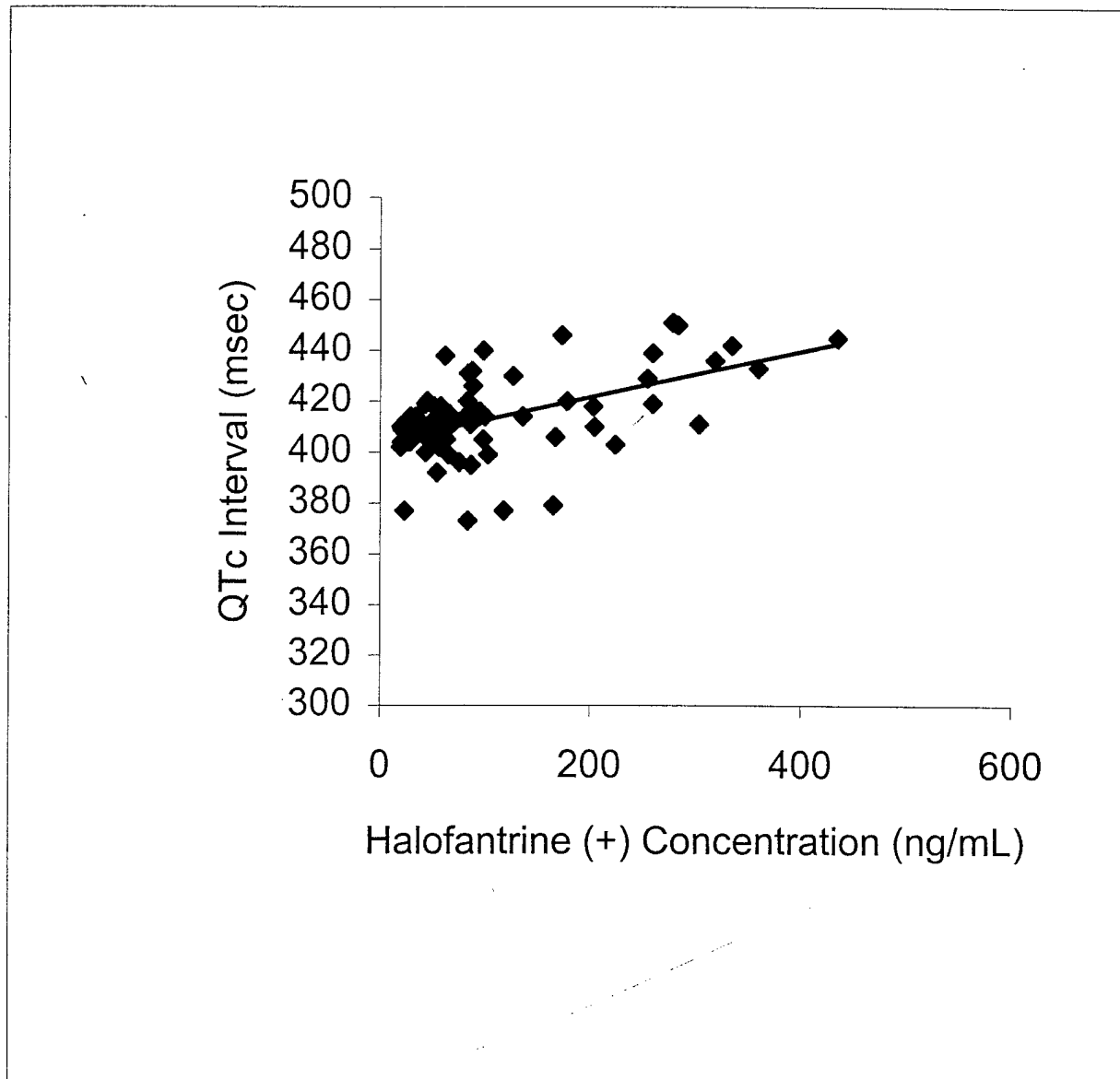


Figure 63b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 10

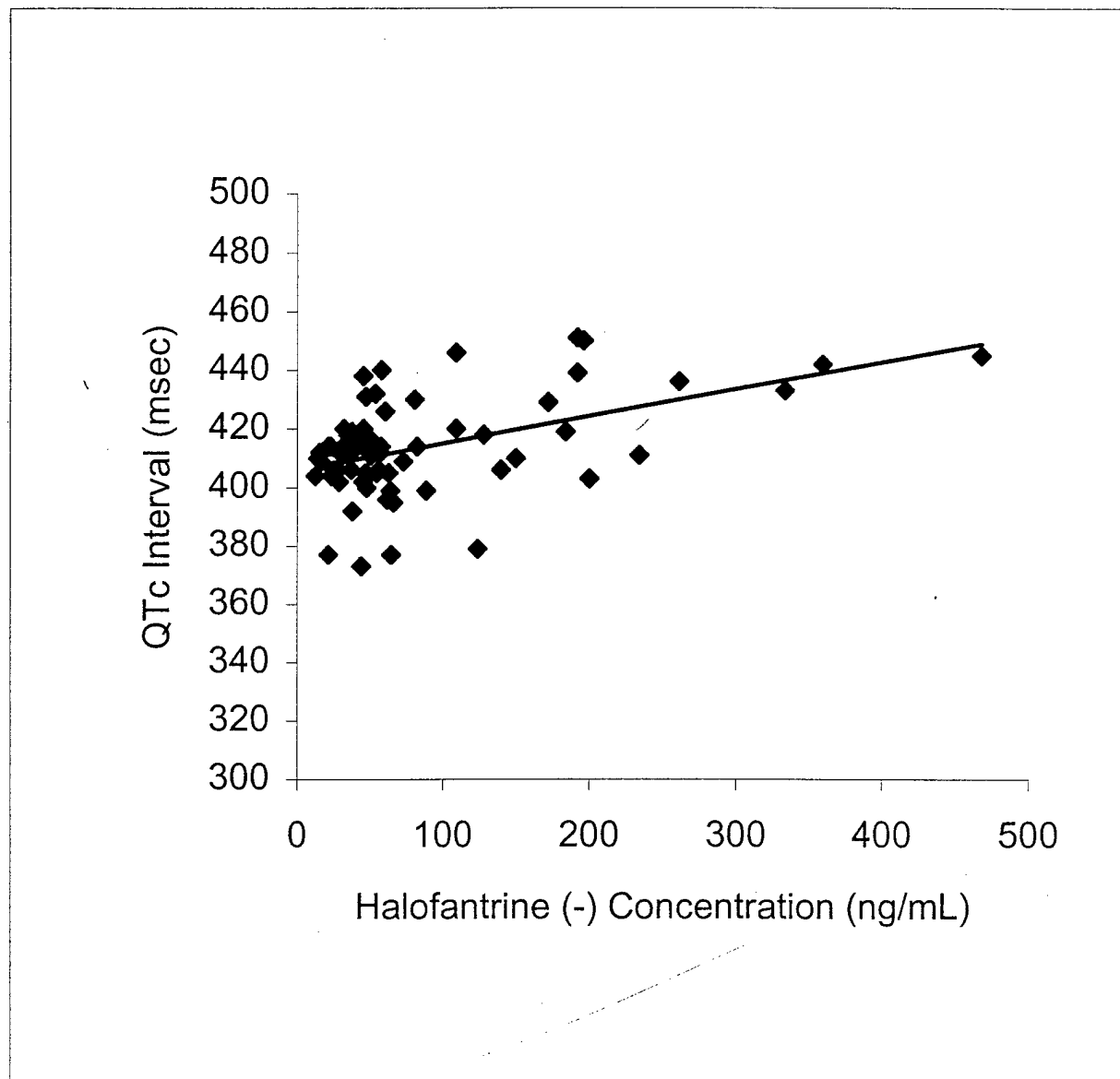
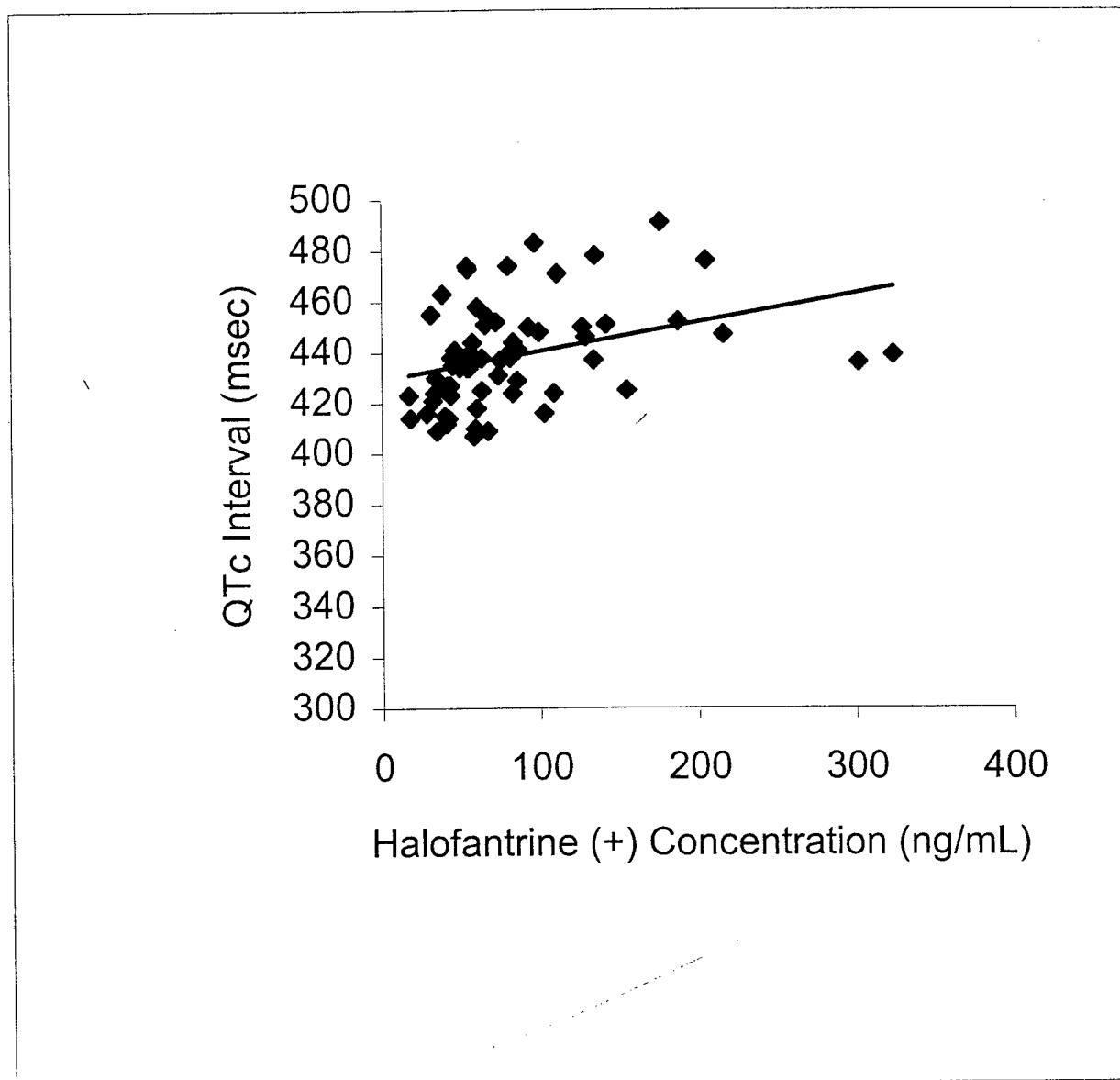


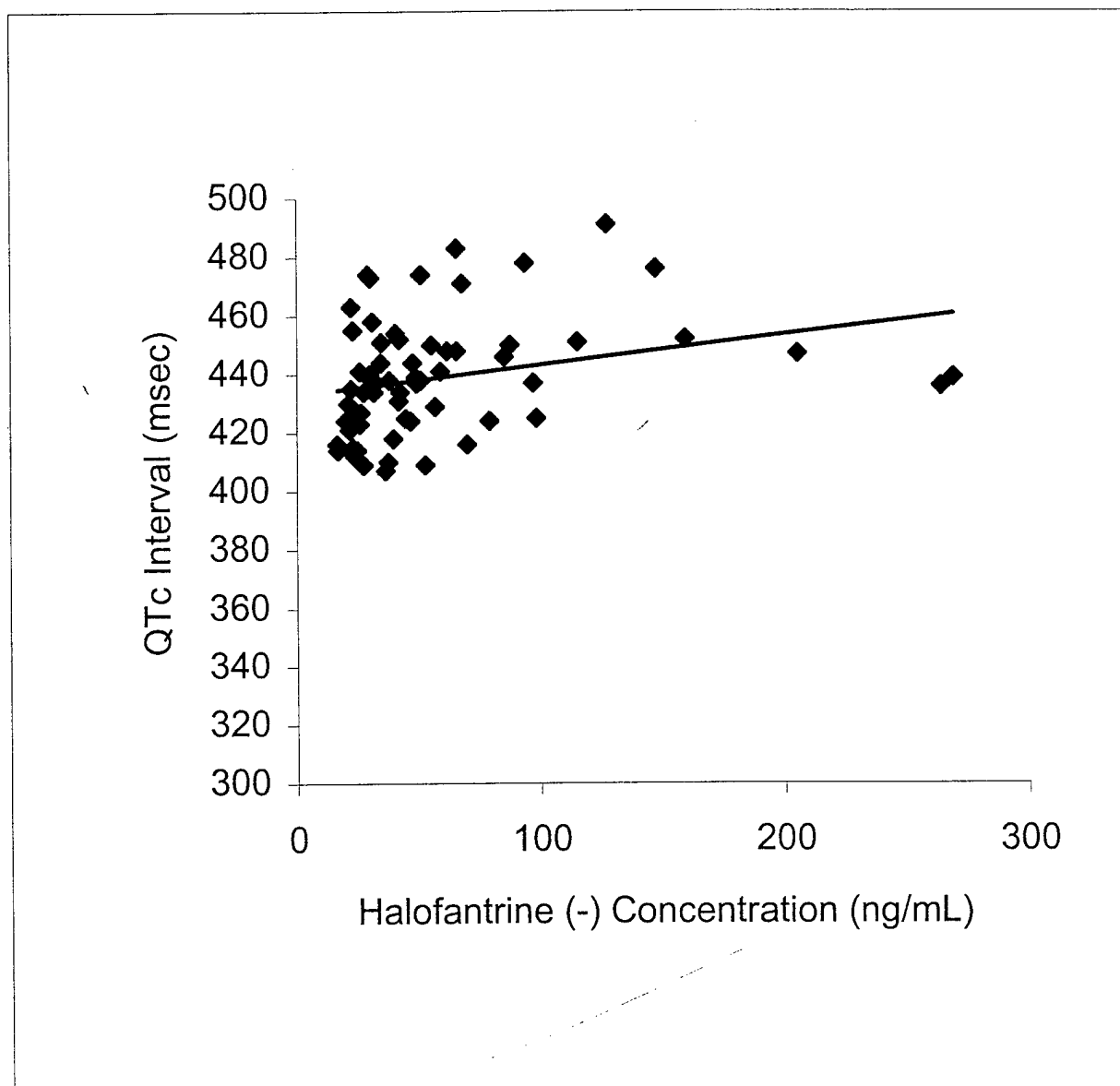
Figure 64a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 11



$$QTc = 429.4 + 0.1126 * \text{Halo}(+)$$

Correlation Coefficient (r) = 0.339

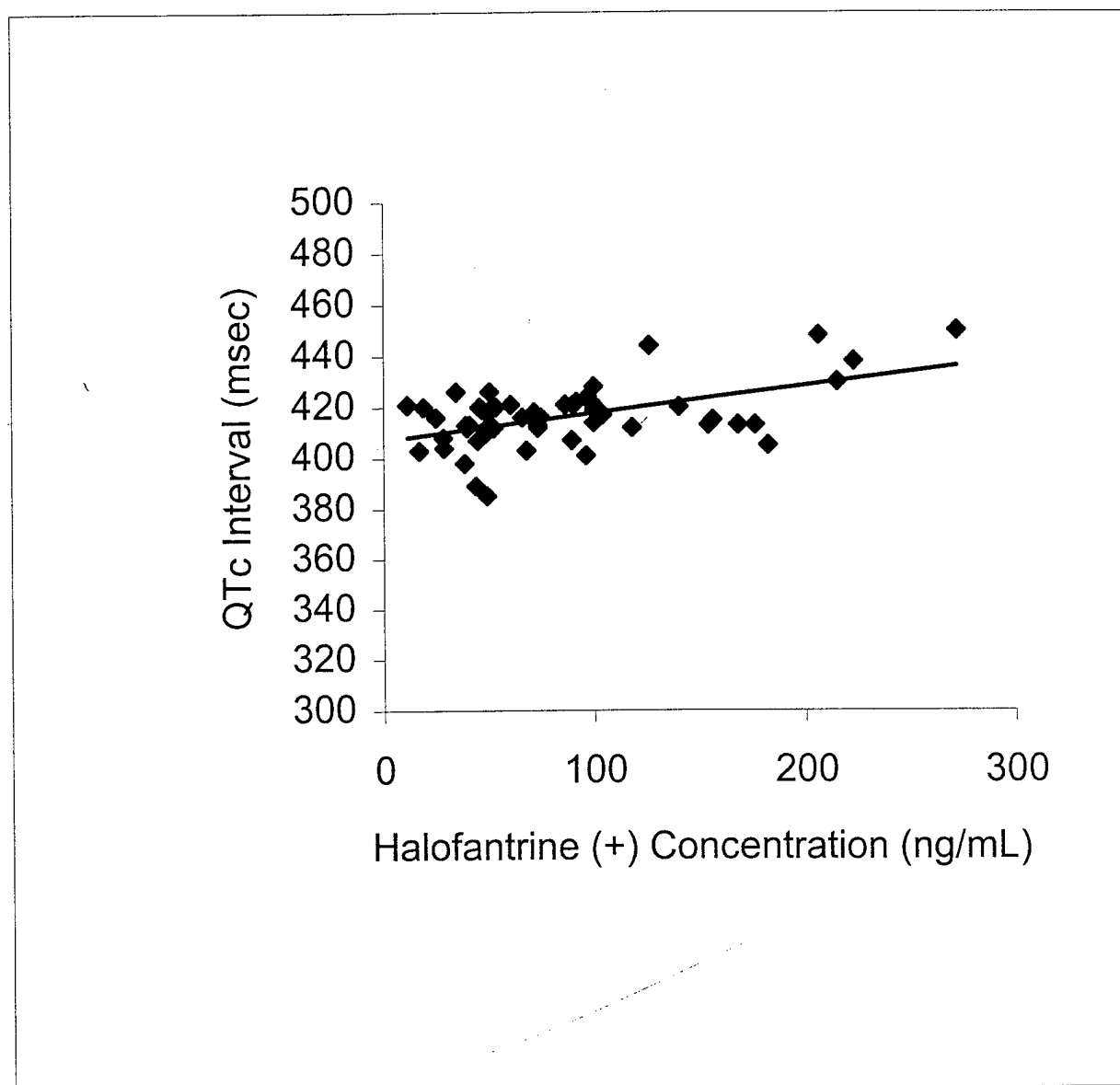
Figure 64b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 11



$$QTc = 433.0 + 0.1025 * \text{Halo}(-)$$

Correlation Coefficient (r) = 0.268

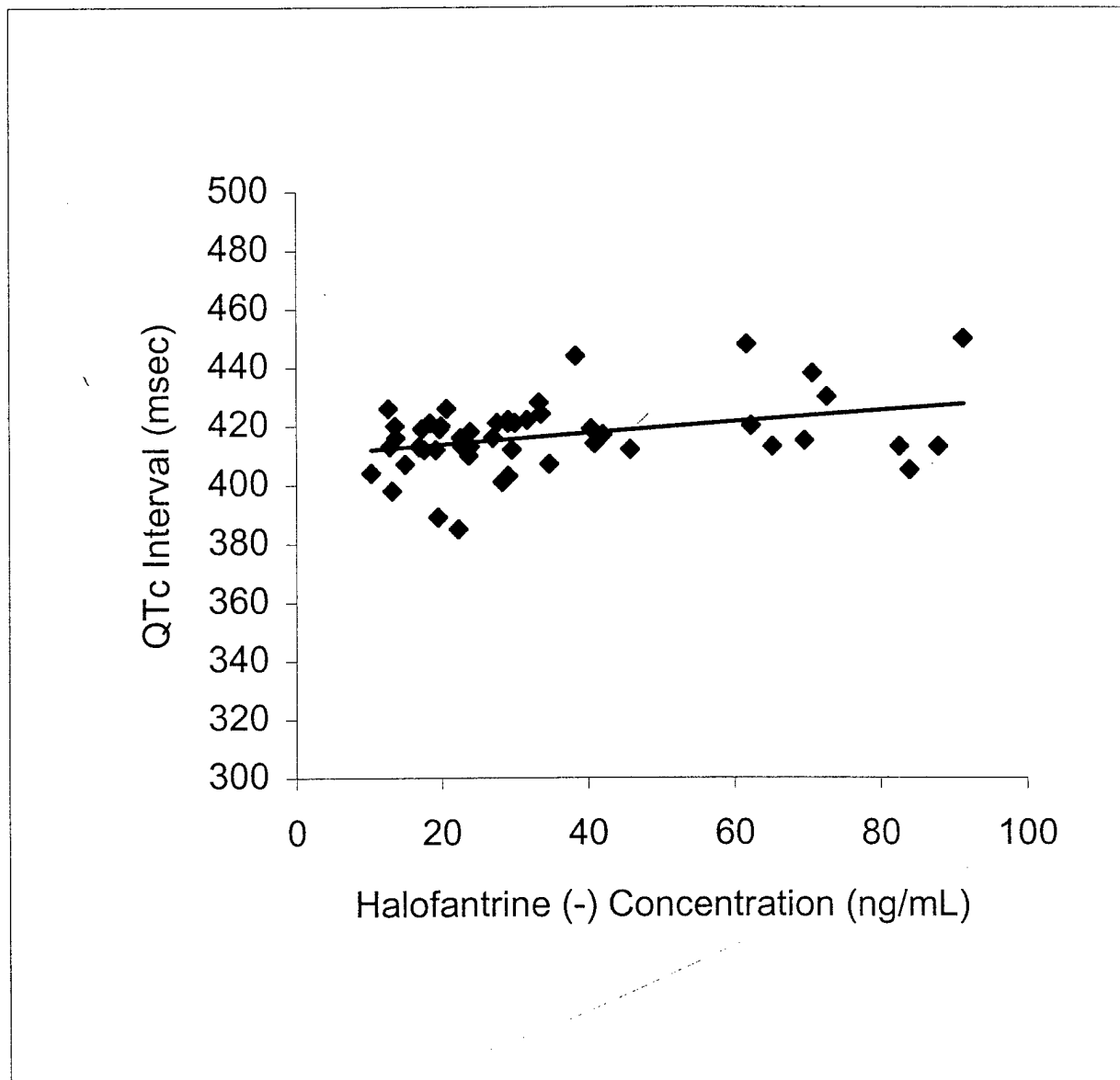
Figure 65a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 14



$$QTc = 407.0 + 0.1075 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.522$$

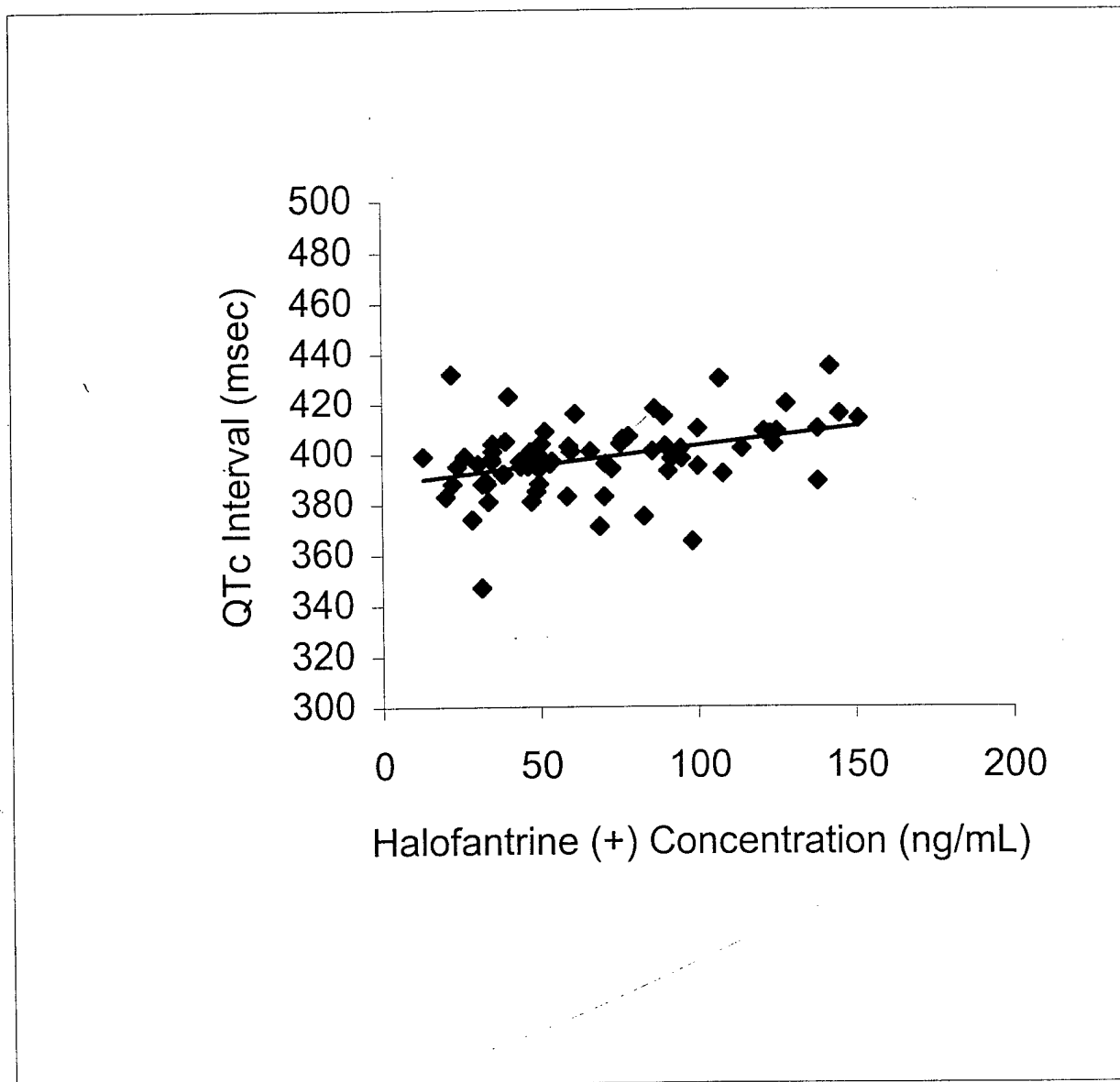
Figure 65b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 14



$$QTc = 409.9 + 0.1938 * \text{Halo}(-)$$

Correlation Coefficient (r) = 0.352

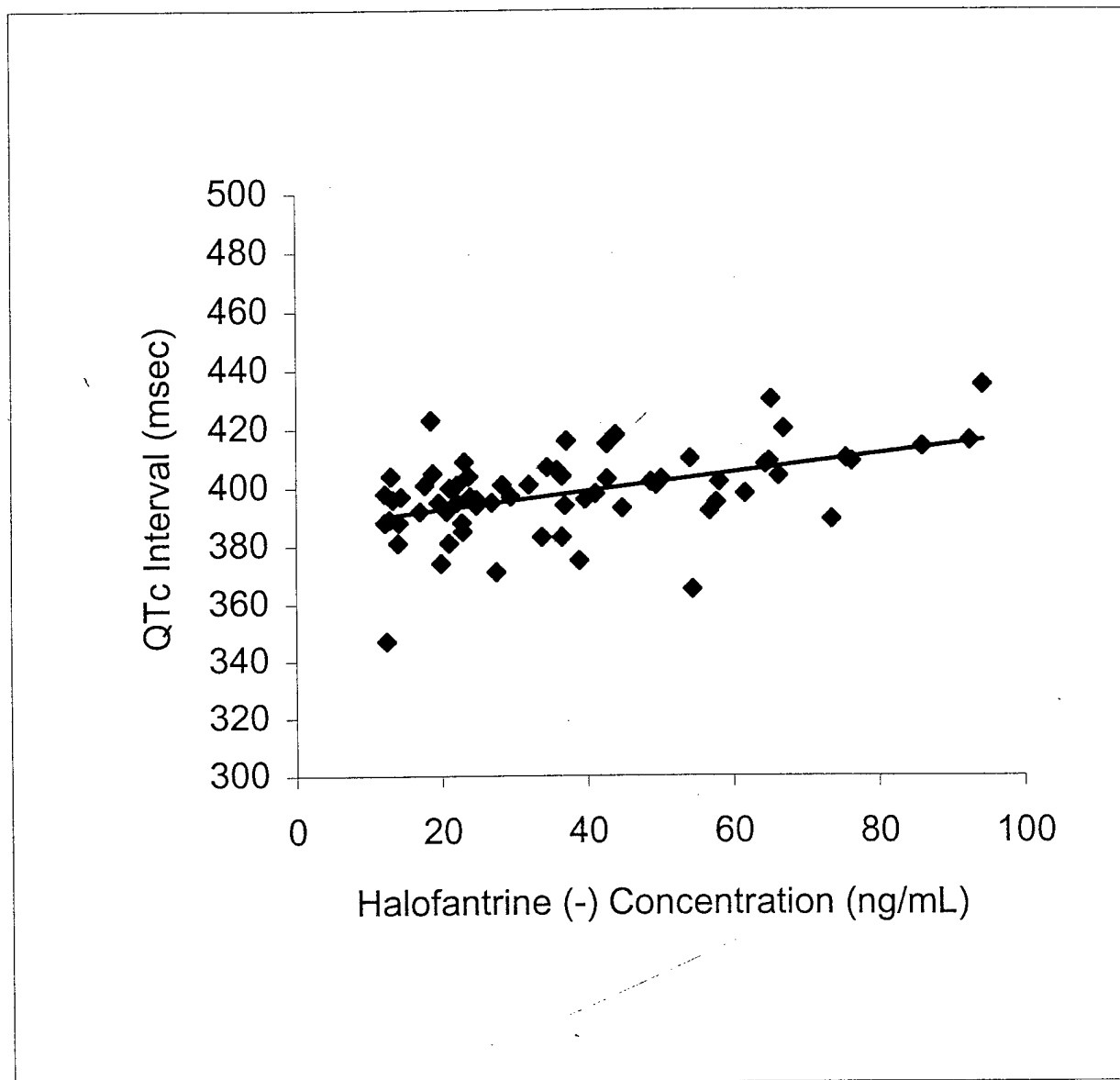
Figure 66a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 15



$$QTc = 387.9 + 0.1539 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.379$$

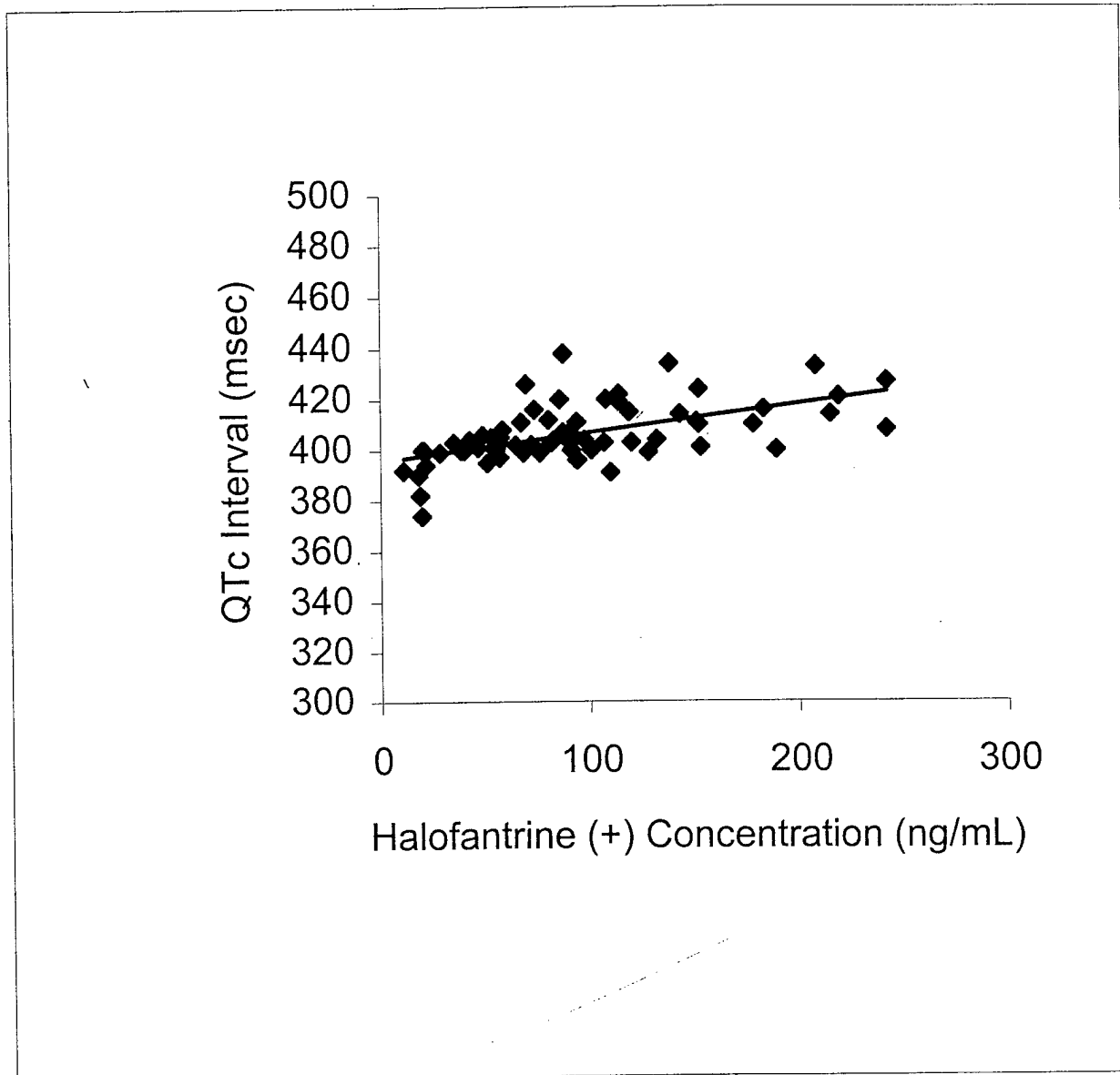
Figure 66b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 15



$$QTc = 386.2 + 0.3180 * \text{Halo}(-)$$

Correlation Coefficient (r) = 0.472

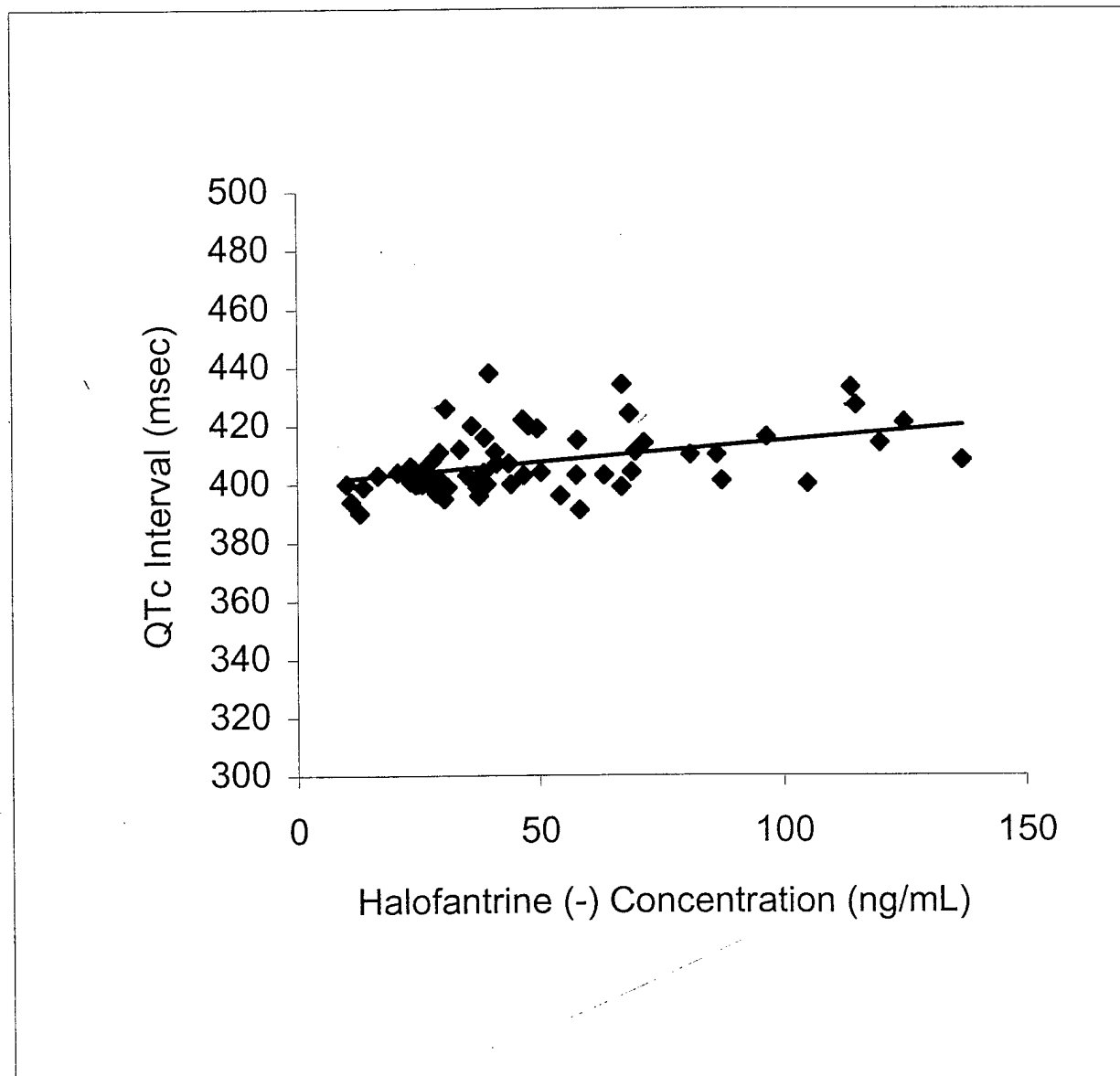
Figure 67a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 16



$$QTc = 395.7 + 0.1125 * Halo(+)$$

$$\text{Correlation Coefficient } (r) = 0.555$$

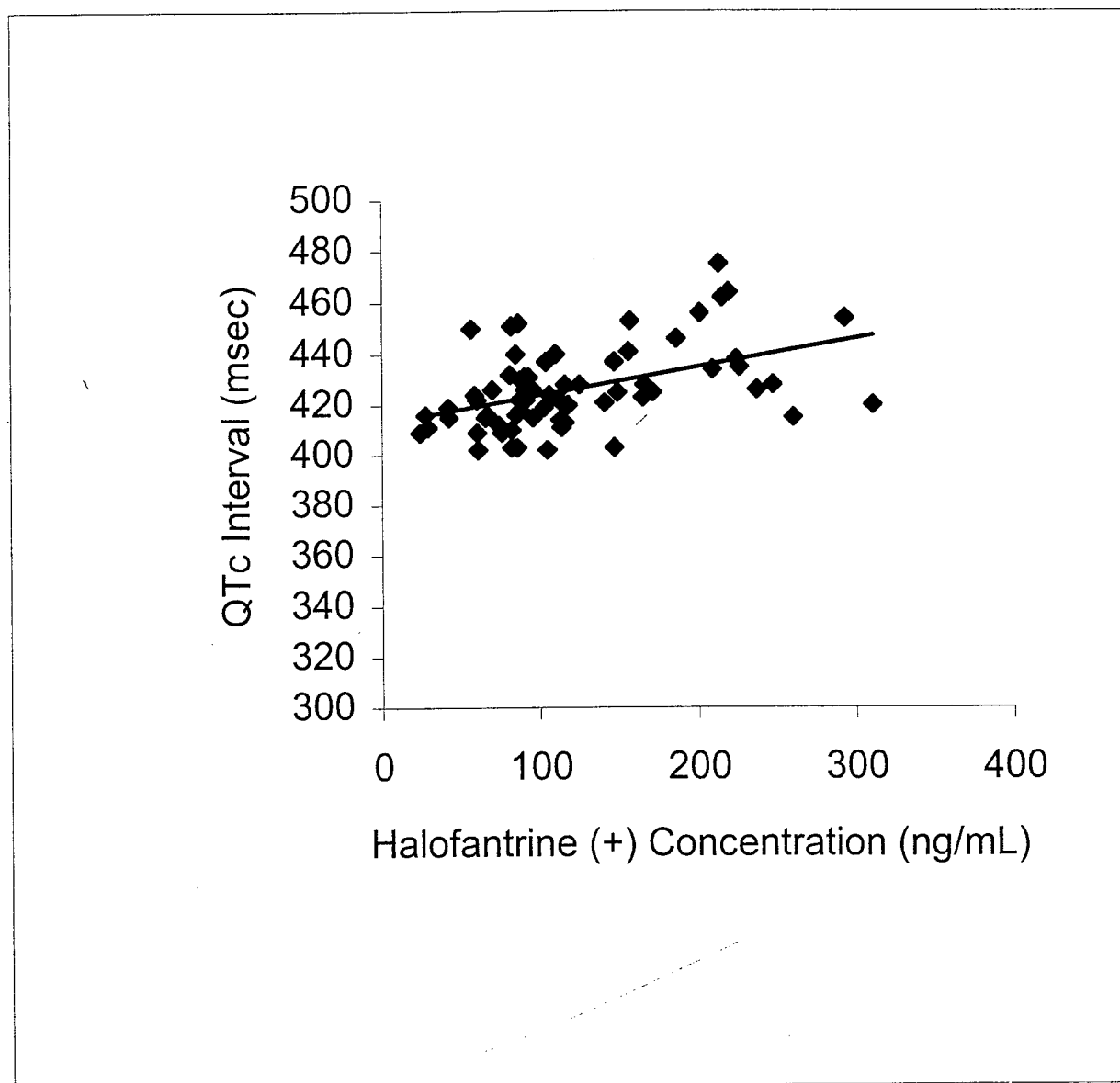
Figure 67b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 16



$$QTc = 400.4 + 0.1452 * Halo(-)$$

Correlation Coefficient (r) = 0.415

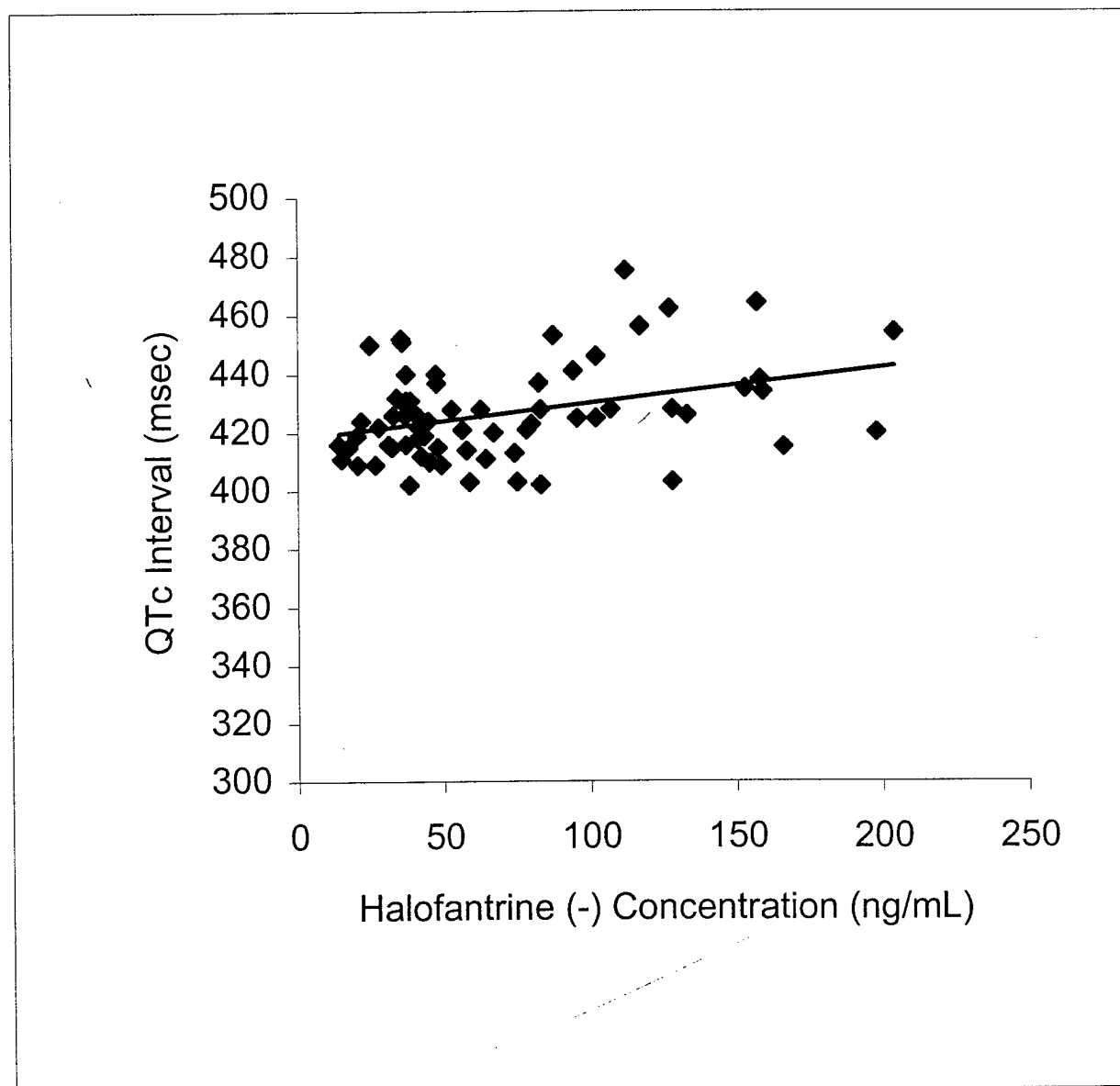
Figure 68a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 18



$$QTc = 412.8 + 0.1112 * Halo(+)$$

$$\text{Correlation Coefficient (r)} = 0.455$$

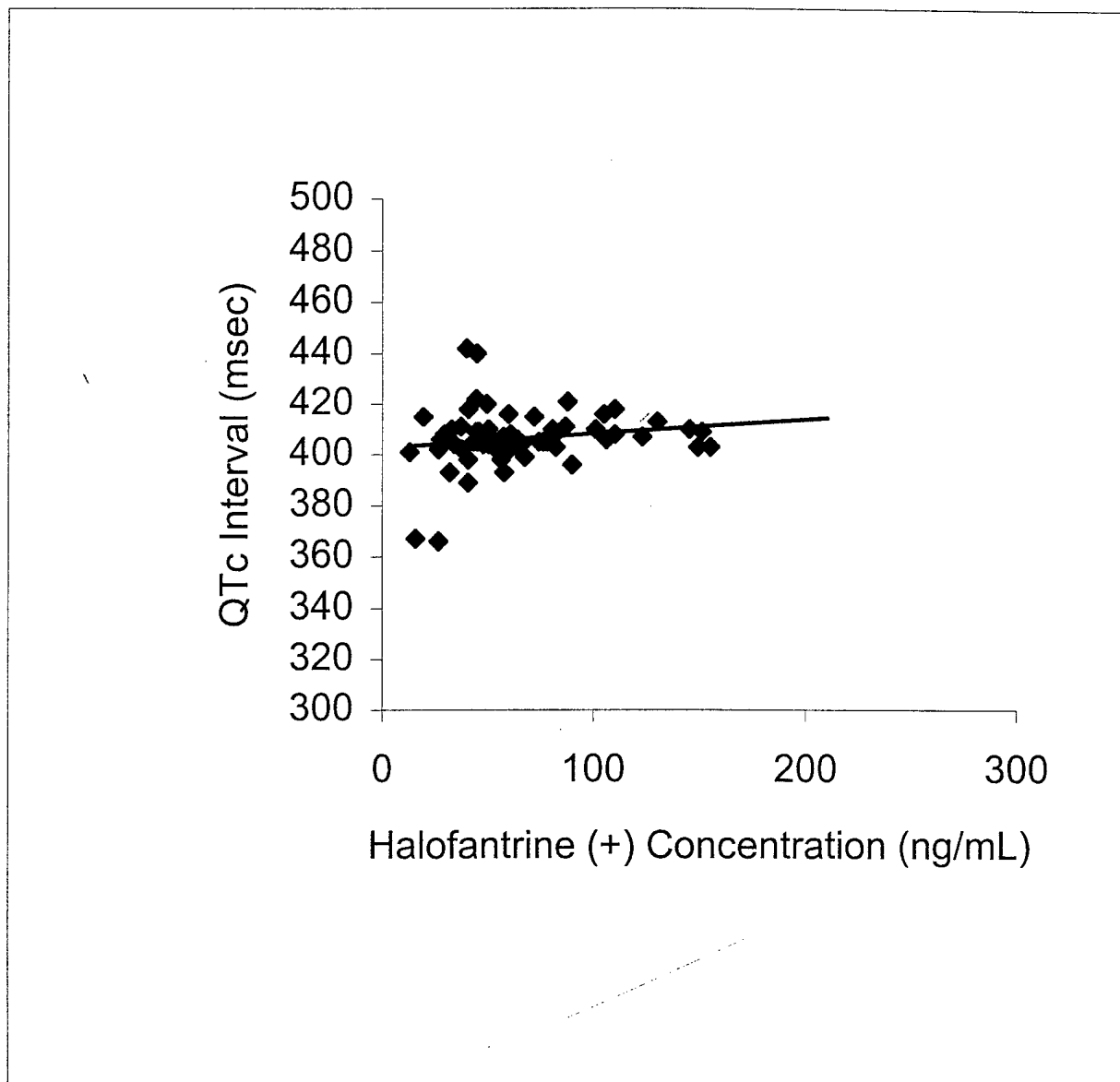
Figure 68b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 18



$$QTc = 418.1 + 0.1203 * Halo(-)$$

Correlation Coefficient (r) = 0.349

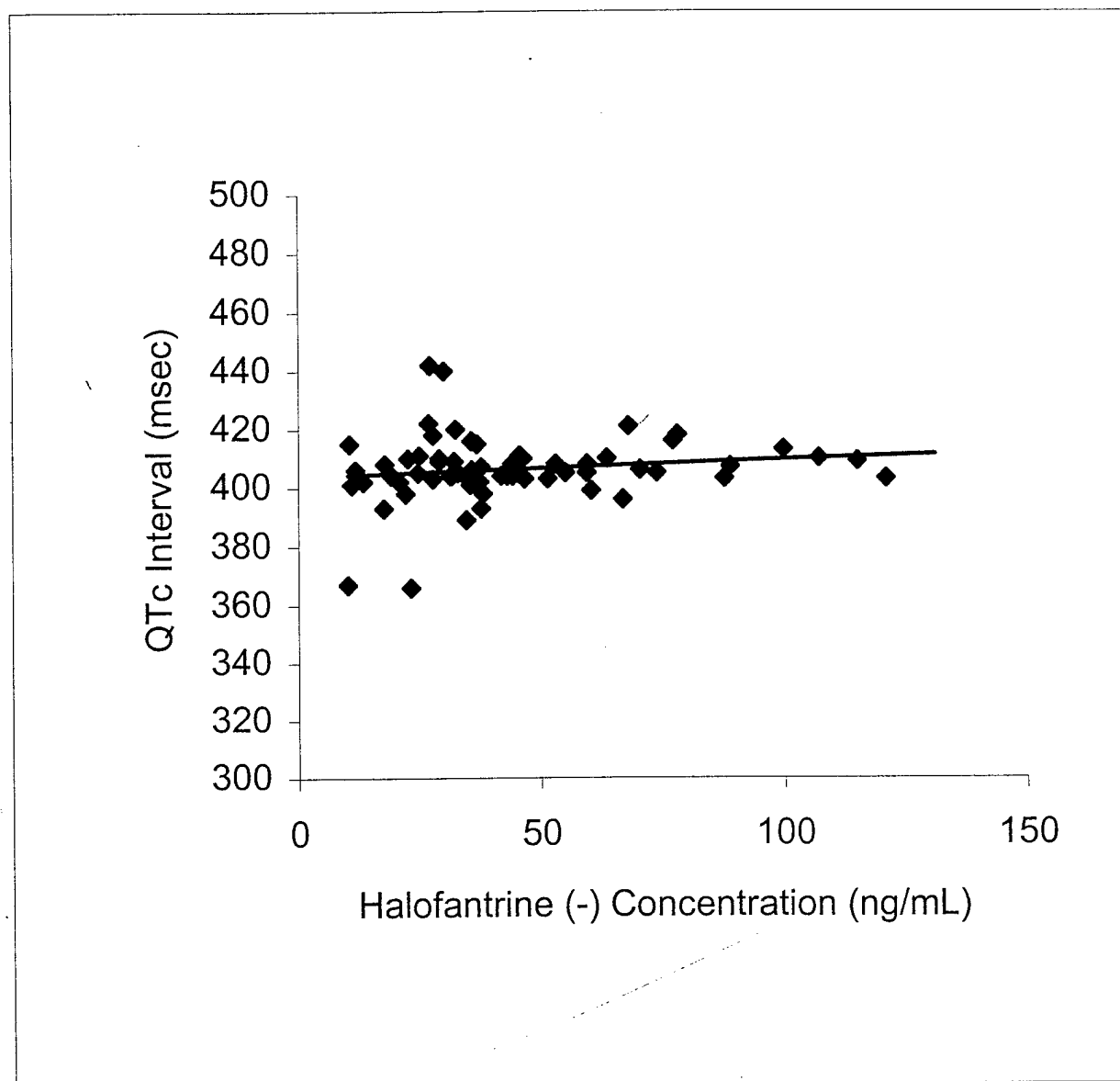
Figure 69a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 19



$$QTc = 402.6 + 0.0566 * Halo(+)$$

Correlation Coefficient (r) = 0.168

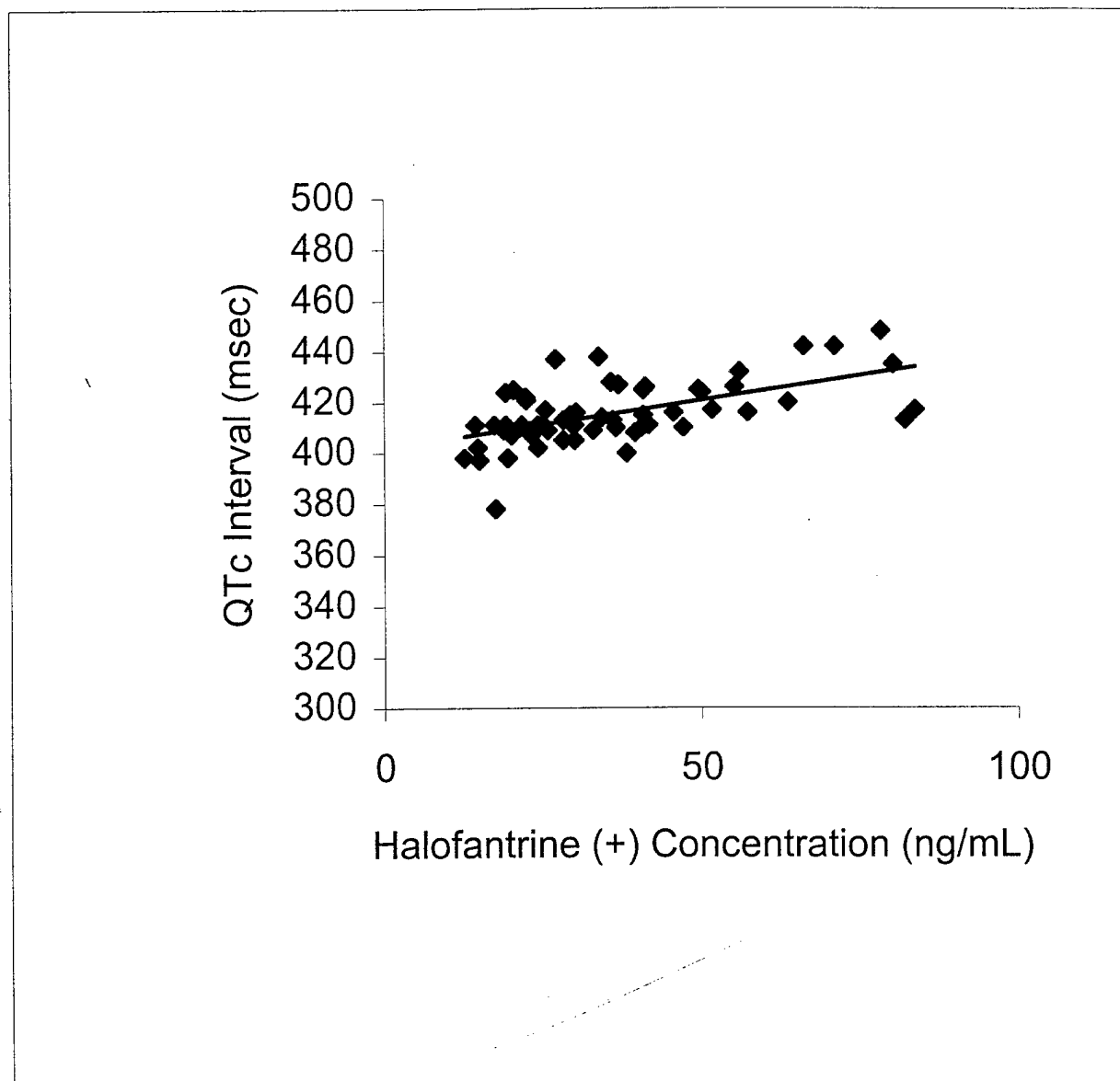
Figure 69b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 19



$$QTc = 403.8 + 0.0583 * Halo(-)$$

Correlation Coefficient (r) = 0.131

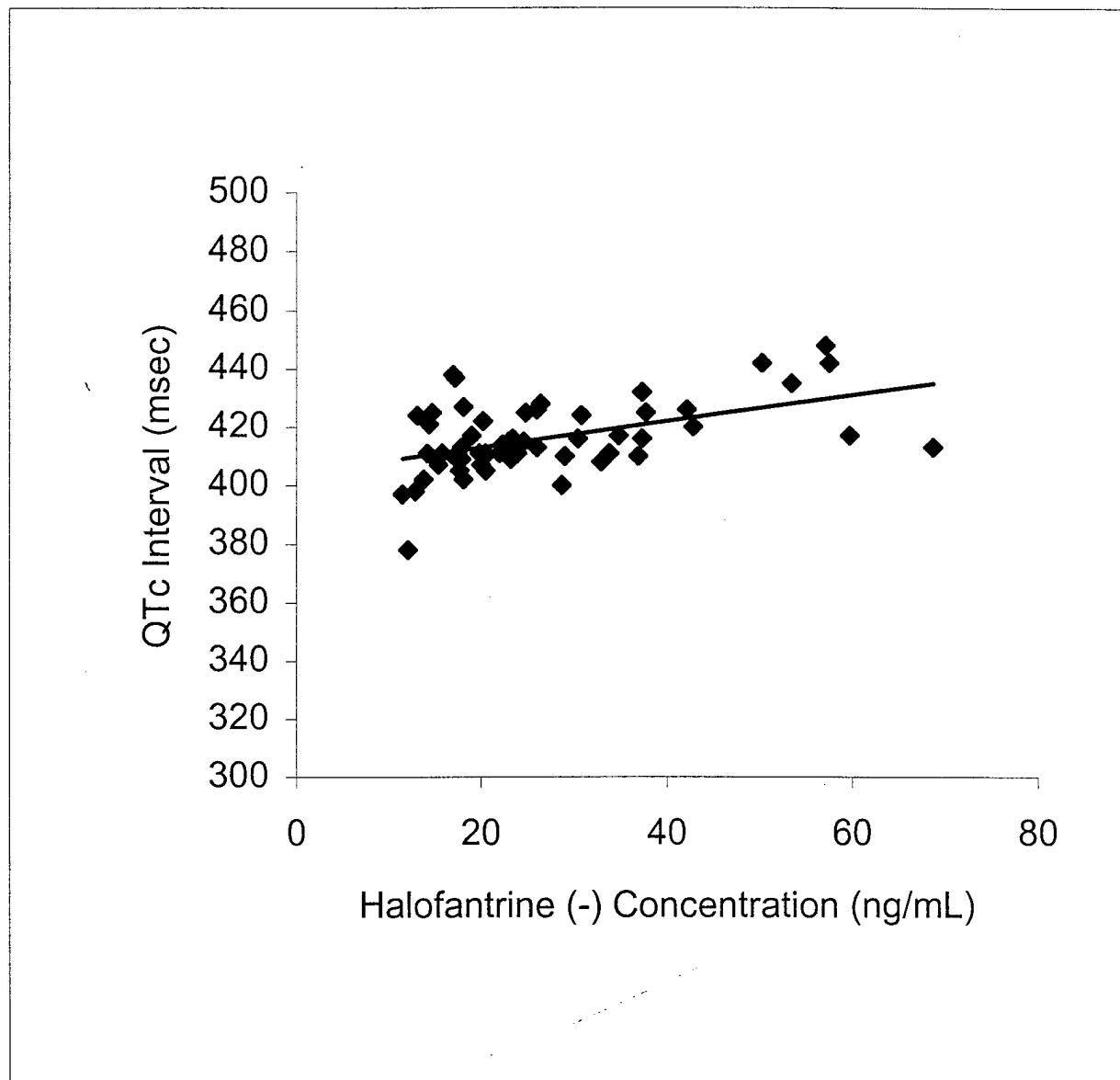
Figure 70a: QTc Intervals vs. Halofantrine (+) Concentration for Subject 20



$$QTc = 401.6 + 0.3849 * Halo(+)$$

$$\text{Correlation Coefficient (r)} = 0.567$$

Figure 70b: QTc Intervals vs. Halofantrine (-) Concentration for Subject 20



$$QTc = 404.0 + 0.4512 * \text{Halo}(-)$$

Correlation Coefficient (r) = 0.487